1 2 3 4 5 6 7 8 9 10 11 12 13 14	RoB BONTA Attorney General of California RENU GEORGE (SBN: 262310) Senior Assistant Attorney General KARLI EISENBERG (SBN: 281923) Supervising Deputy Attorney General KATHLEEN BOERGERS (SBN: 213530) Supervising Deputy Attorney General ERICA CONNOLLY (SBN: 288822) Deputy Attorney General HAYLEY PENAN (SBN: 313693) Deputy Attorney General 1300 I Street, Suite 125 P.O. Box 944255 Sacramento, CA 94244-2550 Telephone: (916) 210-7755 Fax: (916) 327-2319 E-mail: Erica.Connolly@doj.ca.gov Attorneys for Plaintiff People of the State of California SUPERIOR COURT OF THE S COUNTY OF A	
15 16 17	THE PEOPLE OF THE STATE OF CALIFORNIA,	Case No.
18 19	Plaintiff, v.	COMPLAINT FOR PERMANENT INJUNCTION, CIVIL PENALTIES, AND OTHER EQUITABLE RELIEF
20	HEARTBEAT INTERNATIONAL, INC.,	(Bus. & Prof. Code §§ 17200, et seq., 17500, et seq.)
21	REALOPTIONS, DOES 1-100, INCLUSIVE,	[VERIFIED ANSWER REQUIRED PURSUANT TO CODE CIV. PROC. §
22	Defendants.	446]
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2	Plaintiff, the People of the State of California, by and through Attorney General Rob	
3	Bonta ("Plaintiff" or "the People"), alleges the following, on information and belief:	
4	<b>INTRODUCTION</b>	
5	1. For the vast majority of pregnant people who choose to undergo an abortion, their	
6	most common emotion is relief. <sup>1</sup> For a significant percentage of those people, medication	
7	abortion is their preferred method of exercising their reproductive choice. The standard	
8	medication abortion regime, consisting of two medications, mifepristone and misoprostol, has	
9	been proven to be incredibly safe-safer than Penicillin, Viagra, and even some over-the-counter	
10	drugs like Tylenol. <sup>2</sup> It is also incredibly effective, with more than 95% of individuals who take	
11	the standard two-dose regime completing their abortion without need for any further	
12	intervention. <sup>3</sup>	
13	2. A vast majority, however, is not everyone. A small percentage of pregnant	
14	people—0.004%—may reconsider their decision while in the midst of a medication abortion. <sup>4</sup> As	
15	1 (Coving II Doors to 1 English & Doorisin Distance Fine Verse Following	
16	<sup>1</sup> (Corinne H. Rocca et al., <i>Emotions &amp; Decision Rightness over Five Years Following an</i> <i>Abortion: An Examination of Decision Difficulty &amp; Abortion Stigma</i> (2020) 248 Soc. Sci. & Med. 112704, https://www.sciencedirect.com/science/article/pii/S0277953619306999?via%3Dihub;	
17 18	see also Lauren Ralph et al., Measuring decisional certainty among women seeking abortion (2017) 95 Contraception 269-78; Diana Greene Foster, The Turnaway Study: Ten Years, A	
19	Thousand Women, and the Consequences of Having—or Being Denied—an Abortion (2021) pp. 124 [describing the seminal study regarding emotions and decision rightness following abortion,	
20	which provides that "at every interview over the five years after their abortion, 95% of women reported that having the abortion was the right decision for them."].)	
21	<sup>2</sup> (Annette Choi & Will Muller, <i>How Safe Is the Abortion Pill Compared with Other</i>	
22	<i>Common Drugs</i> , CNN (Apr. 21, 2023), <u>https://www.cnn.com/2023/03/15/health/abortion-pill-safety-dg/index.html</u> ; Amy Schoenfeld Walker et al., <i>Are Abortion Pills Safe? Here's the</i>	
23	<i>Evidence</i> , N.Y. Times (Apr. 7, 2023), https://www.nytimes.com/interactive/2023/04/01/health/abortion-pill-safety.html.)	
24	<sup>3</sup> (FDA, Full Prescribing Info.: Mifeprex, p. 12, <u>https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf</u> [as of Aug.	
25	16, 2023].)	
26	<sup>4</sup> (See Daniel Grossman et al., <i>Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review</i> (2015) 92 Contraception 206-11	
27	["According to data obtained from Danco Laboratories, the U.S. manufacturer of mifepristone,	
28	less than 0.004% of patients who took mifepristone between 2000 and 2012 ended up deciding to	

1 part of that change of heart, these people likely face emotional turmoil-anxious and unsure 2 about what choices remain open to them. In such a vulnerable state, they need and deserve 3 accurate, scientifically sound information about their options, including the risks involved with 4 those options.

3. 5 Instead of offering vulnerable pregnant people accurate information, Defendants 6 Heartbeat International, Inc. ("HBI") and RealOptions provide them with false and misleading 7 statements. They claim that there is a way to "reverse" the effects of mifepristone, which they call "abortion pill reversal" or "APR." They further claim—falsely—that through APR 8 "thousands of lives" have been "saved."<sup>5</sup> But, there is no evidence showing that mifepristone can 9 10 be "reversed" or that the APR "protocol" contributes to the continuation of a pregnancy.

11 4. Defendants know this. Nevertheless, they regularly continue to advertise and 12 promote APR, and they cite flawed and misleading reports to support their claims.

5. 13 Defendants further misrepresent that APR can be safe and effective if initiated 14 after a pregnant person has taken misoprostol (i.e., the second abortion drug in the two-drug 15 abortion regime), or after taking a different medication abortion drug, methotrexate, or when 16 initiated longer than 72 hours after taking the mifepristone dose. There are **no studies** suggesting 17 APR is effective or safe in those situations.

18 6. Defendants falsely imply to patients that APR is safe, even though the only 19 credible study on APR suggests potentially significant health risks. Defendants fail to disclose 20 these potential risks, which can arise from stopping a medication abortion midway. They also fail 21 to disclose the potential for unknown risks, which, given the absence of long-term data, may not 22 be evident for many years. This information is crucial for pregnant individuals and their families 23 as they decide their next steps in this time-sensitive situation.

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7. In essence, Defendants use emotionally vulnerable individuals who come to them in the midst of a gut-wrenching life choice as subjects in experiments to determine whether APR

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<sup>5</sup> (Heartbeat International, *Abortion Pill Rescue Network*, 28 https://www.heartbeatinternational.org/our-work/apr [as of Aug. 21, 2023].) 3

continue their pregnancies."].) 27

1 is safe and effective. Defendants attract these individuals through multiple misrepresentations 2 and pressure them by claiming they must start treatment as quickly as possible, further exploiting 3 these individuals' heightened emotional state. The People of the State of California bring this suit to end this misconduct. 4 8. 5 PARTIES 6 9. Plaintiff is the People of the State of California. The People bring this action by 7 and through Rob Bonta, Attorney General of the State of California ("Attorney General"). The 8 Attorney General is the chief law officer of the State and has authority to file civil actions to 9 protect public rights and interests. (Const., art. V, § 13; Bus. & Prof. Code, § 321.)<sup>6</sup> The 10 Attorney General is authorized by Business and Professions Code sections 17204 and 17535 to 11 obtain injunctive relief to halt violations of, and enforce compliance with, Business and 12 Professions Code section 17200 et seq., and Business and Professions Code section 17500 et seq., 13 respectively. The Attorney General is authorized by Business and Professions Code sections 14 17206 and 17536 to obtain civil penalties of up to \$2,500 for each violation of sections 17200 et 15 seq. and 17500 et seq., respectively. The Attorney General brings this challenge pursuant to his 16 independent constitutional, statutory, and common law authority to represent the public interest. 17 10. Defendant Heartbeat International, Inc. ("HBI") is a 501(c)(3) charitable 18 organization that operates the "most expansive network" of "pro-life pregnancy resource centers" 19 and has "over 3,000 affiliated pregnancy help locations," including over 2,000 locations throughout the United States.<sup>7</sup> HBI is incorporated and has its principal place of business in 20 21 Columbus, Ohio. HBI owns and operates the Abortion Pill Rescue Network ("APRN") as well as 22 the Abortion Pill Reversal ("APR") hotline. Defendant RealOptions ("RealOptions") is a 501(c)(3) non-profit organization that 23 11. 24 is incorporated in California, has a principal place of business in San Jose, and operates five 25 clinics in California. RealOptions operates the clinics under the name "RealOptions Obria 26 <sup>6</sup> All further statutory references are to California statutes. 27 <sup>7</sup> (Heartbeat International, *Our Mission & Vision*, 28 https://www.heartbeatinternational.org/about/our-passion [as of Aug. 21, 2023].)

Medical Clinics." Two of RealOptions' clinics are located in San Jose; one clinic is located in
 Union City; one clinic is located in Oakland; and one clinic is located in Redwood City.
 RealOptions advertises APR as a service available at all five of its clinics.

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12. The true names and capacities of Defendants sued herein as DOES 1 through 100,
inclusive, are unknown to the People, who therefore sue said Defendants by such fictitious names.
When the true names and capacities of said Defendants have been ascertained, the People will ask
leave of the court to amend this Complaint to insert in lieu of such fictitious names the true names
and capacities of said fictitiously named Defendants.

9 13. At all relevant times, Defendants have controlled, directed, formulated, known,
10 and/or approved of, and/or agreed to the various acts and practices of each of the Defendants.

11 14. Whenever reference is made in this Complaint to any act of any Defendant or
 12 Defendants, such allegation means that such Defendant or Defendants did the acts alleged in this
 13 Complaint either personally or through the Defendant's officers, directors, employees, agents,
 14 and/or representatives acting within the actual or ostensible scope of their authority.

15 15. Defendants have engaged in a conspiracy, common enterprise, and common
course of conduct, the purpose of which is and was to engage in the violations of law alleged in
this Complaint. The conspiracy, common enterprise, and common course of conduct continue to
the present.

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# JURISDICTION AND VENUE

16. This Court has jurisdiction over the People's claims pursuant to article VI, section
10 of the California Constitution and Business and Professions Code sections 17204, 17206,
17535, and 17536.

17. This Court has personal jurisdiction over Defendants because each Defendant
intentionally avails itself of the California market so as to render the exercise of jurisdiction by
California courts consistent with traditional notions of fair play and substantial justice. Defendant
RealOptions additionally is incorporated in and has a principal place of business in California and
therefore resides in the state. Since 2008, defendant HBI has been registered with the California
Secretary of State as doing business in the state. HBI has multiple affiliated clinics in California,

1	and a number of those affiliates, including RealOptions, offer APR as a medical service. On	
2	information and belief, HBI refers pregnant individuals who contact its APR hotline or livechat t	
3	its California-based affiliates that offer APR services.	
4	18. The violations of law alleged in this Complaint occurred in the Counties of San	
5	Mateo, San Jose, Alameda, and throughout California.	
6	19. Venue is proper in Alameda County pursuant to Code of Civil Procedure section	
7	393, subdivision (a) because Defendant RealOptions operates a medical clinic offering APR	
8	within this county, in Oakland, and HBI advertises APR to the public and Abortion Pill Rescue	
9	Network Training to potential affiliates within the county. Accordingly, at least some part of the	
10	cause of action arose within this county. (See Code Civ. Proc., § 393, subd. (a).)	
11	FACTUAL ALLEGATIONS	
12	I. "ABORTION PILL REVERSAL"	
13	20. Abortion pill reversal ("APR") is an experimental protocol that Defendants claim	
14	is "safe" and "effective" for "reversing" a medication abortion when a pregnant person has taken	
15	the first drug, mifepristone, but before having taken the second drug, misoprostol, in the standard	
16	two-drug medication abortion regime. Mifepristone blocks the effects of progesterone and	
17	thereby inhibits the continuation of the pregnancy. Misoprostol, which is taken 24-48 hours after	
18	the mifepristone, causes the uterus to contract and expel the remaining pregnancy tissue,	
19	completing the abortion.	
20	21. As HBI explains the process, the APR "protocol" directs a patient to take high	
21	doses of progesterone within 72 hours of taking mifepristone to try to "reverse" the effects of the	
22	mifepristone. Although HBI uses the term "reverse" and "reversal," the theory underlying APR	
23	is more akin to a "competition" between progesterone and mifepristone. Even APR's proponents	
24	acknowledge that APR cannot truly "reverse" mifepristone, such as by acting as an antidote.	
25	22. As of the date of this filing, not a single credibly designed medical study has	
26	verified HBI's claims.	
27	23. According to HBI, the APR "protocol" requires the pregnant person who has taken	
28	mifepristone to be administered a high dose of progesterone in one of three ways: orally,	

vaginally, or through intramuscular injection. The pregnant person is also advised not to take the
second drug in the medication abortion regimen, misoprostol. The "protocol" calls for treatment
with progesterone to be tapered after the first three days, and then to continue until the end of the
first trimester. Under this "protocol," the dosage and frequency of progesterone differs depending
on the route of administration.

6 24. HBI offers similar "protocols" of high-dose progesterone administration for
7 pregnant individuals who have taken <u>both</u> drugs in the standard medication abortion regime
8 (mifepristone and misoprostol). As of the date of this filing, no medical study has verified this
9 protocol.

10 25. HBI also offers similar "protocols" of high-dose progesterone administration for 11 those pregnant individuals who have taken methotrexate, a separate drug that can be used to 12 induce an abortion. Unlike mifepristone, however, methotrexate inhibits folic acid rather than 13 progesterone. For the "attempted reversal of methotrexate" "protocol," HBI advises providers to 14 also administer leucovorin and folic acid to counteract the effects of the methotrexate—another 15 "protocol" which has never been studied.

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II.

#### 2012 CASE SERIES AND 2018 REPORT

17 26. The original APR "protocol" for pregnant people who have completed only the
18 first step in a medication abortion (i.e., taken only mifepristone) was conceptualized by two
19 providers, Dr. George Delgado and Dr. Matthew Harrison. Harrison purportedly first used
20 progesterone in 2006 on a pregnant patient who had taken mifepristone but did not want to
21 continue with a medication abortion. In 2008, Delgado, a California-based family physician and
22 HBI's medical advisor, devised the APR "protocol" described above.

27. To support the APR "protocol," in 2012, Delgado and Dr. Mary Davenport, a
 California-licensed physician and the current medical director of RealOptions' Redwood City and
 Oakland locations, published a case series review ("2012 Case Series").<sup>8</sup> In the 2012 Case Series,
 they described the administration of progesterone to seven pregnant women who had taken
 <sup>8</sup> (George Delgado & Mary Davenport, *Progesterone Use to Reverse the Effects of*

28 *Mifepristone* (2012) 46 Pharmacotherapy 1723.)

mifepristone, six of whom were included in the case series' analysis and four of whom carried
their pregnancies to full-term, reportedly with no birth defects. The progesterone route of
administration and dosage varied among the women included in the case series, and there was no
control group.

28. 5 Despite the small sample size, the presence of confounding variables, and the lack 6 of control group, Delgado nevertheless concluded that "[t]he experience of these patients suggests 7 that medical abortion can be arrested by progesterone injection after mifepristone ingestion prior 8 to misoprostol" and that further research was necessary only "to have an evidence basis for the 9 best protocol."<sup>9</sup> The 2012 Case Series, however, was insufficient evidence for these conclusions. 10 29. In May 2012, Delgado created the Abortion Pill Reversal Network, consisting of 11 an APR website (www.abortionpillreversal.com) and a telephone hotline (1-800-712-HELP), 12 through which he promoted APR and sought to connect pregnant people who have initiated a 13 medication abortion with providers willing to administer the APR protocol. He collected data on 14 individuals who contacted the hotline, especially those individuals who opted to pursue APR. 15 30. Using this hotline patient data, in 2018, Delgado, Davenport, and others wrote an article ("2018 Report"), labeling it "an observational case series of 754 patients."<sup>10</sup> According to 16 17 the 2018 Report, 1,668 calls were received by the hotline from June 24, 2012 to June 21, 2016. 18 Of these 1,668 callers, 754 pregnant individuals initiated the experimental progesterone 19 treatment. The 2018 Report claimed to have tracked the pregnancy outcomes to ultimately conclude, "[t]he reversal effects of Mifepristone using progesterone is safe and effective."11 20 21 31. As an AMA Journal of Ethics article explained, case series like the 2012 Case Series and the 2018 Report (which claimed to be a case series), "describe characteristics of 22 patients with certain diseases and may help identify questions for future research" but "are ranked 23 24 lower than other [study] designs because of associated bias, lack of random sampling, the absence 25 <sup>9</sup> (*Ibid.*) 26 <sup>10</sup> (George Delgado et al., A case series detailing the successful reversal of the effects of mifepristone using progesterone (2018) 33 Issues L. Med. 21-31.) 27  $^{11}$  (*Ibid.*) 28

of controls or a comparison group, and heterogeneity of subjects."<sup>12</sup> Because case series provide 1 2 only weak scientific evidence, they are not commonly used to make changes in how medications 3 are used. Instead, they are used to inform further studies with more rigorous methodologies. 4 32. As Delgado and Davenport have acknowledged, the 2018 Report has serious 5 design flaws that undermine classifying it even as a "case series," further underscoring that the 6 report is not credible scientific evidence to support a conclusion that APR is either safe or 7 effective as a treatment for the continuation of a pregnancy after administration of mifepristone. 8 These design flaws include, but are not limited to, the following: 9 The 2018 Report did not report outcomes on all participants. This is a key a. failing. The Report purported to observe "754 patients," but only included 10 11 547 patients in the analysis. The Report explains that three groups were 12 excluded: (1) those who had taken misoprostol prior to taking 13 progesterone or who had taken mifepristone more than 72 hours prior to 14 initiating progesterone; (2) those with whom Delgado lost contact; and (3) 15 those who ultimately chose to complete the medication abortion or opt for 16 surgical abortion. The Report did not observe or study the outcomes of 17 these excluded groups (i.e. 207 patients). That constitutes nearly a third of 18 the total pregnant people observed. 19 The Report used flawed data. To show that APR was effective, the Report b. 20 needed to show a more successful embryo survival rate with the use of 21 progesterone than without the use of progesterone. But, the Report used 22 flawed data that made the rate of embryo survival without progesterone 23 look artificially low, which in turn made the embryo survival rate with 24 progesterone look misleadingly high. 25 26 <sup>12</sup> (Opeyemi Daramola & John Rhee, *Rating Evidence in Medical Literature* (Jan. 2011) 27 AMA J. Ethics, https://journalofethics.ama-assn.org/article/rating-evidence-medicalliterature/2011-01.) 28

1	c. The Report says nothing about whether APR had negative health effects on	
2	the pregnant person. Nothing in the Report suggests that Delgado tracked	
3	patients to see if they had such adverse effects. Without that tracking, the	
4	Report says nothing about—and therefore cannot be used to tout—the	
5	safety of the APR "protocol."	
6	d. The Report has misleading results. The Report differentiated the APR	
7	"success rates" based on the dosage of progesterone and how the drug was	
8	administered. The "success rates" range from an overall rate of 48% to	
9	68% for oral progesterone to 64% for progesterone injections. <sup>13</sup> None of	
10	those rates account for different gestational ages of the pregnancies (i.e.,	
11	pregnancy length determined by the number of weeks following the	
12	pregnant person's last menstrual period). <sup>14</sup> Mifepristone becomes less	
13	effective the longer an individual is pregnant, meaning that for further-	
14	along pregnancies, progesterone may not have made a difference to the	
15	embryo surviving. In short, it is misleading to lump into one "success rate"	
16	pregnancies that were at different stages.	
17	33. Due to its flaws and weaknesses, the 2018 Report does not establish causation	
18	between the APR protocol and the continuation of pregnancies for the women tracked in the	
19	Report. In other words, the study does not show whether their pregnancies were just as likely to	
20	have continued without the APR protocol as with it.	
21	34. In addition, Delgado and Davenport appear not to have timely secured the	
22	necessary institutional oversight to conduct their research on human subjects. Delgado and	
23	Davenport appear to have obtained institutional review board ("IRB") approval only after they	
24		
25	<sup>13</sup> The 68% statistic is from the highest dosage of oral progesterone, which only 31 individuals received out of the total 119 who received oral progesterone. The 64% statistic is	
26	from progesterone injections and was calculated by combining all individuals who received intramuscular injections into one category, regardless of the dosage received.	
27	<sup>14</sup> The 2018 Report did track embryo survival rates by gestational age, but it did not factor gestational age into the survival rates attributed to each method of administering progesterone.	
28		

conducted their research, meaning there was no institutional oversight during the course of their
 experiment.<sup>15</sup> Such oversight is important to secure *before* beginning medical experiments on
 human subjects because an IRB helps ensure ethical treatment of and reduction of risks to those
 human subjects.<sup>16</sup>

5 35. The 2018 Report failed to adequately disclose Delgado's potential conflicts of
6 interest. The sources of the data in the 2018 Report were patient contacts to Delgado's Abortion
7 Pill Reversal Network hotline and live chat, but the 2018 Report does not disclose that fact.
8 Instead, it states only that "[s]ubjects called an informational hotline linked to an informational
9 website and staffed by nurses and a physician assistant," with no disclosure of Delgado's
10 connection.<sup>17</sup>

36. Delgado and Davenport knew about the flaws and weaknesses in the 2018 Report.
Even after Davenport and Delgado had collected the data from incoming calls to Delgado's
hotline, Davenport acknowledged that a rat study provided stronger evidence than the hotline
data. That Davenport made this assessment after completing the data collection demonstrates that
even the Report's authors understood that their data was not sufficient to make the claims in the
Report.

37. As a reflection of these flaws, three journals—the Annals of Emergency Medicine,
the Journal of the American Board of Family Medicine, and the Annals of Pharmacotherapy—
rejected the 2018 Report for publication. The medical journal that ultimately published the 2018
Report—Issues in Law & Medicine—is a publication sponsored by two anti-abortion
organizations and, as Delgado has admitted, is "not particularly well-known in the medical field."

 <sup>&</sup>lt;sup>15</sup> (Daniel Grossman & Kari White, *Abortion "Reversal" — Legislating without Evidence* (Oct. 18, 2018) 379 N. Eng. J. Med. 1491-93.)

 <sup>26 &</sup>lt;u>training/lesson-3-what-are-irbs/index.html#:~:text=Membership%20%3E%20Quiz%20Questions-</u>
 27 <u>Purpose%20of%20IRBs,and%20adequately%20protect%20research%20participants.</u>)

<sup>28 &</sup>lt;sup>17</sup> (George Delgado et al., *A case series detailing the successful reversal of the effects of mifepristone using progesterone* (2018) 33 Issues L. Med. 21-31.)

(Planned Parenthood of Tenn. & N. Mississ. v. Slatery (M.D. Tenn. 2021) 523 F.Supp.3d 985,
 994.)

3 38. Despite these acknowledged flaws and its failure to establish causation between
4 the APR protocol and pregnancy continuation, the 2018 Report is the seminal "study" cited in
5 support of the safety and efficacy of APR by Defendants HBI and RealOptions.

Given its substantial deficiencies, the 2018 Report cannot be considered a study by
any stretch. It is certainly not a rigorous scientific study of the effectiveness and safety of APR.
As described more fully below, the only rigorous study on APR suggested potentially significant
health risks arising from stopping a medication abortion after taking mifepristone, an essential
step in the APR "protocol."

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III.

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## SAFETY CONCERNS, CONTRARY EVIDENCE, AND CRITICISMS OF ABORTION PILL Reversal Protocol

40. Further underscoring the lack of credibility of Delgado and Davenport's 2012 Case
Series and 2018 Report are multiple articles using rigorous scientific methodology, which call
into question the conclusions that the 2012 Case Series and 2018 Report reached about the safety
and effectiveness of APR.

17 41. For example, a 2015 systematic literature review ("2015 Literature Review") 18 published in *Contraception*, a peer-reviewed medical journal, found that there was a lack of 19 evidence that pregnancy continuation after administration of mifepristone was more likely after 20 treatment with progesterone as compared with expectant management (i.e., not administering 21 misoprostol and monitoring the pregnancy). The 2015 Literature Review further found that in 22 published studies the percentage of pregnancies that continued after only mifepristone administration (but no progesterone) ranged from 8-46%.<sup>18</sup> This review, authored by experts in 23 24 obstetrics, gynecology, and public health at the University of California, San Francisco, 25 University of Alabama at Birmingham, University of Michigan, Johns Hopkins, Stanford 26 University, and the University of North Carolina, concluded that "[i]n the rare case that a woman 27 <sup>18</sup> (Daniel Grossman et al., Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review (2015) 92 Contraception 206-11.) 28

1	changes her mind after starting medical abortion, evidence is insufficient to determine whether		
2	treatment with progesterone after mifepristone results in a higher proportion of continuing		
3	pregnancies compared to expectant treatment [i.e., waiting for spontaneous miscarriage]."		
4	42. The 2015 Literature Review also included analysis of the 2012 Case Series,		
5	finding that the 2012 Case Series "was of poor quality and lacked clear information on patient		
6	selection." <sup>19</sup>		
7	43. A 2018 article published in the New England Journal of Medicine analyzed the		
8	2018 Report in detail in the context of commenting on state laws requiring physicians to discuss		
9	APR with patients. That article described APR as an "unmonitored research experiment" and		
10	observed: "It is difficult to compare the results from [the 2018 Report] with data on mifepristone		
11	alone for several reasons," including the exclusions of patients by some of the providers because		
12	the embryo had died following the pregnant patient taking mifepristone and exclusions of patients		
13	who were lost to follow up before 20 weeks, both of which "probably exaggerated the treatment's		
14	reported success." <sup>20</sup>		
15	44. A 2019 comment published in <i>Contraception</i> , a peer-reviewed medical journal, by		
16	Dr. Mitchell Creinin, identified numerous flaws in the 2018 Report: "lack of control groups, no		
17	confirmation of mifepristone ingestion, failure to establish viability prior to progesterone		
18	treatment, and providing experimental treatment without patient consent or institutional review		
19	board oversight." <sup>21</sup>		
20	45. In light of the lack of credible evidence on its safety and effectiveness, medical		
21	associations have highlighted concerns about APR:		
22			
23			
24	<sup>19</sup> ( <i>Ibid</i> .)		
25	<sup>20</sup> (Daniel Grossman & Kari White, <i>Abortion "Reversal"</i> — <i>Legislating without Evidence</i> (Oct. 18, 2018) 379 N. Eng. J. Med. 1491-93.)		
26	<sup>21</sup> (Mitchell D. Creinin & Melissa J. Chen, <i>Mifepristone antagonization requires real</i>		
27	studies to evaluate safety and efficacy (Nov. 14, 2019) 100 Contraception 427-29, https://www.contraceptionjournal.org/article/S0010-7824(19)30450-0/fulltext.)		
28	12		
	13		

1	a.	The American College of Obstetricians and Gynecologists ("ACOG")	
2	stated: "Claims regarding abortion 'reversal' treatment are not based on		
3	science and do not meet clinical standards. The American College of		
4	Obstetricians and Gynecologists (ACOG) ranks its recommendations on		
5	the strength of the evidence, and does not support prescribing progesterone		
6	to stop a medical abortion." <sup>22</sup>		
7	b.	In a challenge to North Dakota's law requiring physicians to tell patients	
8		that medication abortion may be "reversible," the American Medical	
9		Association ("AMA") stated that "[t]he Compelled Reversal Mandate	
10		forces physicians to tell their patients that medication abortions may be	
11		reversible, a claim wholly unsupported by the best, most reliable scientific	
12		evidence, contravening their ethical and legal obligations as medical	
13		providers." <sup>23</sup>	
14	с.	The Society of Obstetricians and Gynaecologists of Canada has stated that	
15		it "does not support prescribing progesterone to stop a medical abortion"	
16		and that "[t]he claims regarding so-called abortion 'reversal' treatments are	
17		not based on scientific evidence." <sup>24</sup>	
18	d.	The Royal College of Obstetricians and Gynaecologists, the Faculty of	
19		Sexual and Reproductive Healthcare, the Royal College of Midwives, and	
20		the British Society of Abortion Care Providers have stated that "[t]here are	
21		no reputable national or international clinical guidelines that	
22	<sup>22</sup> (ACOG, Facts are Important: Medication Abortion "Reversal" Is Not Supported by		
23	Science, https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-		
24	<u>supported-by-science</u> [as of Jan. 31, 2022, 2:29 PM].) <sup>23</sup> ( <i>Am. Med. Ass 'n v. Stenehjem</i> (June 25, 2019, No. 1:19-cv-125) [412 F. Supp. 3d 1134]		
25	[complaint at 2], <u>https://www.ama-assn.org/system/files/2019-06/ND-mife-reversal-</u> complaint.pdf.)		
26	<sup>24</sup> (Soc. Obstetricians and Gynaecologists of Canada, SOGC Statement on Abortion		
27	Medication "Reversal" (Mar. 19, 2021), <u>https://sogc.org/en/content/featured-news/SOGC Statement on Abortion Medication Reversal.aspx.</u> )		
28			
		14	

1	recommend the use of progesterone to reverse the effect of		
2	mifepristone, and no evidence that it increases the likelihood of continuing		
3	pregnancy, compared to expectant management alone." <sup>25</sup>		
4	46. The first (and only) randomized clinical study to attempt to test the safety and		
5	efficacy of APR was initiated at the University of California, Davis in 2019 but had to be halted		
6	due to serious "safety concerns" after 3 of the 12 enrolled study participants "experienced severe		
7	bleeding, requiring ambulance transport to an emergency department." <sup>26</sup> Because the study was		
8	cut short, the researchers were unable to "quantify the full extent of the hemorrhage risk." <sup>27</sup> The		
9	lead researcher, however, has cautioned that "[w]omen who use mifepristone for a medical		
10	abortion should be advised that not following up with misoprostol could result in severe		
11	hemorrhage, even with progesterone treatment." <sup>28</sup>		
12	47. In addition to the medical community's criticisms, three federal district courts,		
13	having evaluated expert evidence from APR proponents and critics, have found that the 2018		
14	Report does not establish causation between the APR protocol and pregnancy continuation. (See		
15	All-Options, Inc. v. Atty. Gen. of Ind. (D. Ind. 2021) 546 F.Supp.3d 754, 766; Planned		
16	Parenthood of Tenn. & N. Mississ., 523 F.Supp.3d at 1003-04; Am. Med. Ass'n v. Stenehjem		
17	(D.N.D. 2019) 412 F.Supp.3d 1134, 1150.)		
18			
19	<sup>25</sup> (Royal College of Obstetricians & Gynaecologists, et al., Joint Statement on "Abortion Reversal" (July 7, 2022), <u>https://www.rcog.org.uk/media/nbahkgvo/rcog-fsrh-abortion-reversal-position-statement.pdf.</u> )		
20	<sup>26</sup> (UC Davis Health, Can the abortion pill be reversed? A novel search for answers (Dec.		
21	4, 2019), <u>https://providervideos.ucdavis.edu/news/can-the-abortion-pill-be-reversed-a-novel-search-for-answers</u> ; see also Jessica Washington, <i>Study of "Abortion Reversal" Pill Halted</i>		
22	Because It's Too Dangerous, Mother Jones (Dec. 6, 2019),		
23	<u>https://www.motherjones.com/politics/2019/12/study-of-abortion-reversal-pill-halted-because-its-too-dangerous/;</u> Kayla Epstein, <i>Some lawmakers push 'abortion reversal' treatments. A study</i>		
24	shows how dangerous they are, Wash. Post (Dec. 24, 2019), https://www.washingtonpost.com/health/2019/12/24/some-lawmakers-push-abortion-reversal-		
25	treatments-new-study-shows-how-dangerous-they-are/.)		
26 27	<ul> <li><sup>27</sup> (UC Davis Health, Can the abortion pill be reversed? A novel search for answers (Dec. 4, 2019), <u>https://providervideos.ucdavis.edu/news/can-the-abortion-pill-be-reversed-a-novel-search-for-answers.</u>)</li> </ul>		
28	<sup>28</sup> ( <i>Ibid.</i> )		
I	15		

1 48. The 2012 Case Series' and 2018 Report's failure to establish the efficacy of APR 2 is even more problematic in light of the potential—albeit small—risks from the administration of 3 supplemental progesterone. As an expert in American Medical Association v. Stenehjem 4 explained, supplemental progesterone is associated with maternal depression, cholestatic 5 jaundice, and hypertension. That expert also noted that certain studies have raised concerns 6 (though not conclusively) about possible associations between certain progesterone preparations 7 and second trimester miscarriages and stillbirths. With no credible evidence showing that APR is 8 effective, the treatment essentially exposes pregnant individuals to the risks of supplemental 9 progesterone without any benefits.

10

## IV. HBI'S MISLEADING REPRESENTATIONS

49. In April 2018, HBI acquired Delgado's Abortion Pill Reversal Network, including
the <u>www.abortionpillreversal.com</u> website and the APR hotline. Since then, HBI has operated
both as part of its Abortion Pill Rescue Network ("APRN"). Delgado currently is a member of
HBI's medical advisory team.

15 50. HBI continues to operate the website and the hotline and to advertise and promote 16 APR, despite long having knowledge of the unreliable scientific evidence supporting Delgado's 17 "protocol." In its April 2018 press release announcing its acquisition of the Abortion Pill 18 Reversal Network, HBI acknowledged the existence of (and voiced its opposition to) criticisms of 19 APR as being unproven and not backed by credible science. And, in August 2019, HBI 20 intervened in a federal lawsuit challenging a law mandating that abortion providers make 21 disclosures about APR, where it received notice of the September 2019 preliminary injunction 22 order outlining the flaws in the 2018 Report.

51. HBI also has knowledge of the more recent studies and statements about the
unreliability and potential risks of stopping a medication abortion halfway, an essential step in
APR. In September 2021, HBI issued a press release about a Center for Countering Digital Hate
report that included excerpts from the American College of Obstetricians and Gynecologist's
statement about APR; information about the 2018 New England Journal of Medicine article
criticizing the 2018 Report; and information about the 2019 U.C. Davis study that was halted.

Also, in September 2021, APRN's medical director, Brent Boles, posted an entry on the HBI
 website about Google's restrictions of advertisements about APR because the claims were
 "unreliable." In short, for years now, HBI has been fully aware of APR's lack of credible
 scientific support as well as its risks.

5

A.

## Website Representations

52. In addition to <u>www.abortionpillreversal.com</u> ("APR Website"), HBI also operates
the website <u>www.heartbeatinternational.org/our-work/apr</u> ("HBI Webpage"). On both websites,
HBI uses misleading statements as it seeks to persuade pregnant people who have started the
medication abortion process to undergo APR.

10

## Abortionpillreversal.com

11 53. The purpose of the APR Website is to advertise APR to pregnant people, stating: 12 "Have you taken the first dose of the abortion pill? Do you regret your decision and wish you 13 could reverse the effects of the abortion pill? *We're here for you!*" (emphasis in original). HBI 14 encourages potential patients to call its hotline and/or message through its live chat and explains 15 that its hotline and live chat will connect potential patients with medical professionals who will 16 "guide [the patient] towards reversing the effects of the abortion pill."

17 54. Throughout its website, HBI misleadingly uses the terms "reverse" and "reversal."
18 The use of these terms is false and misleading because there is no credible scientific evidence
19 showing that APR "reverses" medication abortions. The terms are also false and misleading
20 because "reverse" and "reversal" do not accurately convey even the theory underlying APR.

55. Amidst its advertisements and attempts to persuade potential patients to undergo
APR, HBI makes additional misleading statements. For example, on multiple pages, HBI states
that APR is an "effective process" because "APR has been shown to increase the chances of
allowing the pregnancy to continue." HBI touts on multiple webpages that "initial studies have
shown" that the success rate for APR is 64-68%. In its drop-down Frequently Asked Questions
page ("FAQs"), HBI also touts that "initial studies have found that the birth defect rate in babies
born after the APR is less or equal to the rate in the general population."

56. These statements are misleading because, as described above, there is no credible
 support for them.

3 57. HBI also misleadingly presents information about the risks from APR. HBI does 4 not provide an FAQ about the possible side effects from APR, such as the risk of severe bleeding. 5 Instead, HBI provides a response to a question about the "possible side effects of progesterone" 6 and lists only mild effects, such as "sleepiness, lack of energy, lightheadedness, dizziness, 7 gastrointestinal discomfort and headaches." The only location where HBI provides any warning 8 about the potential risks of severe bleeding from stopping a medication abortion halfway—an 9 essential step in APR—is in response to two FAQs about "cramping and spotting." 10 58. This information is presented misleadingly because it does not adequately warn 11 individuals of the risks from APR. 12 59. As detailed above, HBI has known or should have known that these statements and 13 presentation of information were misleading. 14 60. HBI further advertises that potential patients should contact the hotline or live chat 15 even if more than 72 hours have passed since they took mifepristone, stating "We are here to 16 help. It may not be too late." This statement is likely to create the impression among potential 17 patients that APR is effective and safe beyond the 72-hour window. 18 61. This statement is misleading because there is no evidence to support it. To the 19 extent HBI relies on the 2012 Case Series and the 2018 Report, those publications looked only at 20 the use of progesterone within a 72-hour window following administration of mifepristone, 21 specifically excluding pregnant individuals who had taken progesterone more than 72 hours after 22 taking mifepristone. *Heartbeatinternational.org/our-work/apr* 23 62. HBI also advertises APR on the Abortion Pill Rescue Network page on HBI's 24 www.heartbeatinternational.org website ("HBI Webpage"). HBI encourages viewers to call its 25 hotline and visit www.abortionpillreversal.com to obtain more information about APR. HBI 26 further touts "women can reach out to the Abortion Pill Rescue Network and be connected with a 27 local medical provider who starts" APR. 28

63. Throughout its website, HBI misleadingly uses the terms "reverse" and "reversal."
 The use of these terms is false and misleading because there is no credible scientific evidence
 showing that APR "reverses" medication abortions. The terms are also false and misleading
 because "reverse" and "reversal" do not accurately convey even the theory underlying APR.

- 64. HBI includes additional misleading statements within these advertisements. For
  example, similar to its misleading statements on its APR Website, HBI touts that a "2018 peerreviewed study showed positive results" and then repeats the 64-68% success rate statistic and
  that there was "no increase in birth defects." HBI also claims that the referenced study showed
  "lower preterm delivery rate than the general population."
- 10 65. Once again, HBI's statements are misleading because there is no evidence to
  11 support them.
- 12 66. As detailed above, HBI has known or should have known that there was no13 credible support for its statements and that the statements were therefore misleading.
- 14 67. HBI makes an additional misrepresentation that "thousands of lives have been 15 saved" through the use of APR. This statement is based primarily on two numbers. First, HBI 16 includes the number of pregnant people who undertook APR and that HBI can confirm remained 17 pregnant at 13 weeks. For those individuals that started APR but HBI cannot confirm remained 18 pregnant at 13 weeks, HBI multiplies the number of those individuals by a 64% success rate, which it obtained from the 2018 Report, and which, as detailed above, is not a reliable statistic.<sup>29</sup> 19 20 In other words, HBI's statement is speculation, not evidence. As a result, HBI's statements are 21 misleading.
- 22

# B. Hotline and Live Chat

68. HBI has a "policies and procedures manual" that it provides to volunteers and
employees that staff its APR hotline and live chat, through which HBI also advertises APR. The
manual includes outlines of information that hotline staff must provide to people who have called,

- 26
- <sup>29</sup> The 64% statistic is unreliable for the additional fact that it relies on providers using
   oral or intramuscular administration of progesterone. Many providers appear to use vaginal
   administration, which even the 2018 Report shows has a lower chance of a pregnancy continuing.

such as explanations of APR and potential side effects, information about misoprostol, the risk of
 birth defects, and APR success rates.

3 69. In this manual, HBI instructs APR hotline staff to make several misleading 4 statements when talking with hotline callers. For example, HBI instructs hotline staff to use the 5 term "reverse" or "reversal" to describe APR. HBI further instructs hotline staff to state that 6 "[i]nitial studies have shown that APR may have a 64-68% success rate." HBI also instructs 7 hotline staff to state that "APR has been shown to increase the chances of allowing the pregnancy 8 to continue." HBI further instructs hotline staff to state that "[i]nitial studies have found that the 9 birth defect rate in babies born after the APR is less than or equal to the rate in the general 10 population." As explained above, however, there is no credible support for any of these 11 statements, and as a result, these statements are misleading.

12 70. HBI also instructs its hotline staff to recommend APR for callers who have already
13 taken both mifepristone and misoprostol or who have taken methotrexate. HBI includes this
14 instruction even though no study has even considered the use of APR for pregnant individuals
15 who had already taken misoprostol or methotrexate. As a result, these statements advertising the
16 use of APR for pregnant people who have taken methotrexate or misoprostol are misleading.

17

#### C. Training Kits

18 71. HBI sells to its affiliates an "APR Healthcare Professional Kit" that will allow
19 those affiliates to advertise and administer APR. The kit consists of an overview of the APR
20 procedure; the progesterone protocols used in APR; frequently asked questions and answers about
21 APR for healthcare professionals and patients; and form templates, including consent forms and
22 outcome report forms. HBI includes several misleading representations within this kit that it
23 encourages its affiliates to use in their advertisements about and administration of APR.

24

#### <u>Protocols</u>

72. HBI provides a "protocol" to attempt reversing a methotrexate medication
abortion. In that "protocol," HBI represents that "for women who have taken methotrexate,
prescribed progesterone may also be beneficial to support the pregnancy even though it is not an
antidote to methotrexate." HBI includes this statement and encourages its affiliates to advertise

and administer APR in these circumstances even though no evidence supports the use of APR for
 pregnant individuals who have taken methotrexate. HBI includes this protocol even as it
 acknowledges that the APR "is designed to serve women who have taken mifepristone
 (Mifeprex)," which shows that HBI knows that APR was not developed for pregnant people who
 have taken methotrexate.

6 73. HBI also provides a "protocol" to attempt reversing a medication abortion after a 7 pregnant person has taken both mifepristone and misoprostol. In that protocol, HBI states that 8 "progesterone may be beneficial to support the pregnancy even though it is not an antidote to 9 misoprostol." HBI includes this statement and encourages its affiliates to advertise and 10 administer APR in these circumstances even though no evidence supports the use of APR for 11 pregnant individuals who have taken misoprostol. HBI includes this protocol even as it 12 acknowledges that APR "is designed to serve women who have taken mifepristone (Mifeprex)," 13 which shows that HBI knows that APR was not contemplated for pregnant people who have taken 14 misoprostol.

15

#### <u>Patient FAQs</u>

16 74. In the kit, HBI also provides "APR Patient FAQs," with answers from Delgado,
17 which are nearly identical to the "Reversal FAQs" appearing on HBI's website. Like the
18 "Reversal FAQs" on HBI's website, the "APR Patient FAQs" include several misleading
19 statements.

20 75. Similar to the APR Webpage, the APR Patient FAQs use the term "reverse" and
21 "reversal" to describe APR. The APR Patient FAQs also state that "[i]nitial studies of APR have
22 shown that APR has a 64-68% success rate" and that "APR has been shown to increase the
23 chances of allowing the pregnancy to continue." The APR Patient FAQs also represent that
24 "[i]nitial studies have found that the birth defect rate in babies born after the APR is less than or
25 equal to the rate in the general population." As explained above, these statements are misleading
26 because there is no credible evidence to support them.

27 76. Like the APR Website, the APR Patient FAQs state in response to the question
28 "[i]s it too late to reverse the abortion pill," that "[t]here have been many successful reversals

when treatment was started within 72 hours of taking the first abortion pill. Even if 72 hours
 have passed, it may not be too late." (emphasis added). This statement implies that APR is
 effective and safe after a 72-hour window following mifepristone administration. This statement
 is misleading because no evidence supports the use of APR for pregnant individuals after 72
 hours have passed.

6

7

8

9

77. Like the APR Website, the APR Patient FAQs misleadingly present the risks associated with APR. These FAQs do not provide an FAQ about the side effects of APR, instead only providing the potential (minor) side effects from progesterone. The FAQs misleadingly present the risk of severe bleeding only under a question about cramping and spotting.

10

## "Informed" Consent Templates

11 78. As part of its training kit, HBI provides template forms for use in securing consent
12 from patients. HBI also provides consent forms based on these templates to pregnant individuals
13 who contact HBI and decide to pursue APR. These consent forms include several misleading
14 statements.

15 79. For example, the "Consent for Patients who took Mifepristone Only" form uses the 16 misleading terms "reverse" and "reversal" and includes the misleading statements that "[i]nitial 17 studies have found that the birth defect rate in babies born after the APR is less than or equal to 18 the rate in the general population"; that "[i]nitial studies of APR have shown that APR has a 64-19 68% success rate"; and that "APR has been shown to increase the chances of allowing the 20 pregnancy to continue." These statements are misleading because there is no credible evidence 21 supporting any of these statements.

80. The "Consent for Patients who took both Mifepristone and Misoprostol" form uses
the misleading terms "reverse" and "reversal" and includes the misleading statement that "for

24 women who have taken the first and second drugs of the medical abortion regimen,

25 mifepristone on day one and misoprostol (Cytotec) 12-48 hours later, progesterone may be

26 beneficial to support the pregnancy even though it is not an antidote to misoprostol."

27 (emphasis in original). These statements are misleading because no evidence supports the use of

28 APR for pregnant individuals who have already taken misoprostol.

81. The "Consent for Patients who took Methotrexate" form uses the misleading terms
 "reverse" and "reversal" and includes the misleading statement that "for women who have taken
 methotrexate, prescribing progesterone may also be beneficial to support the pregnancy
 even though it is not an antidote to methotrexate." (emphasis in original). These statements
 are misleading because no evidence supports the use of APR for pregnant individuals who have
 taken methotrexate.

7

## D. Media Appearances

8 82. HBI executives have made multiple media appearances within the course of their
9 employment in which the executives advertised and made misleading statements about APR.

10 83. For example, on or around May 28, 2020, during the course of their employment, 11 HBI's Director of Medical Impact, Christa Brown, and HBI's Director of Communications and 12 Marketing, Andrea Trudee, appeared on an episode of the Ohio Right to Life: The Push for the 13 Abortion Pill. During their appearance, Brown and Trudee regularly used the terms "reverse" and 14 "reversal" and touted APR and encouraged pregnant people to visit the APR Website to 15 "connect" them to providers. Brown stated that APR is a "cutting edge application of a time-16 tested FDA-approved treatment that's been used for decades to help women who are at risk for 17 preterm delivery or miscarriage." HBI's statement-made through Brown in the course of her 18 employment—misleadingly implies that APR is an FDA-approved treatment, which it is not, and 19 which Brown knew it was not.

84. For her part, Truddee stated that APR has resulted in over 1,000 lives "saved." As
explained above, however, representations about the number of lives "saved" are inherently
misleading given the method HBI uses to reach that number. In short, HBI's statements are based
on speculation, not evidence. As a result, HBI's statements—made through Trudee in the course
of her employment—are misleading.

85. In another example, on or around September 21, 2021, during the course of his
employment, HBI President Jor-El Godsey appeared on an episode of the Help Her Be Brave
podcast. Multiple times during his appearance, Godsey advertised APR by encouraging listeners
to visit the APR Website and to call HBI's hotline to speak with "a number of nurses" and

1 "hopefully connect [the pregnant person] to a local pregnancy center." As he was advertising 2 APR, Godsey repeatedly used the terms "reverse" and "reversal," and cited the 2018 Report and 3 repeated the claim that APR has a 64-68% success rate, going so far as to say "so almost 70, 7 out 4 of 10 women that seek [APR] and get that progesterone in a timely fashion are able to reverse the 5 effects of the abortion pill." As explained above, however, these statements are misleading 6 because there is no credible evidence to support these statements. 7 86. Godsey also made the misleading statement that "over 2,000 babies [] have been 8 saved" via APR. As explained above, however, representations about the number of lives 9 "saved" are based on speculation, not evidence. As a result, HBI's statements-made through 10 Godsey in the course of his employment—are misleading. 11 V. **REALOPTIONS' MISLEADING REPRESENTATIONS** 12 87. RealOptions advertises and administers APR. RealOptions uses HBI-created 13 materials for its APR advertisements. 14 88. Whereas HBI engages in widespread promotion of APR and equips its affiliates 15 and providers with training and materials to administer it, RealOptions is an on-the-ground 16 provider. Through its five clinics, RealOptions is advertising that it will provide APR to pregnant 17 people. 89. 18 In the course of those advertisements and during its administration of APR, 19 RealOptions has made and continues to make misleading statements. 20 A. **Website Representations** 21 90. RealOptions operates the website www.realoptions.net, on which it advertises 22 APR. Through its website, RealOptions seeks to persuade pregnant people who have started the 23 medication abortion process to undergo APR, and in so doing, it makes multiple misleading 24 statements. 25 91. Like HBI does on its websites, RealOptions advertises on its website that APR can 26 "reverse" a medication abortion, that "[i]nitial studies of APR have shown it has a 64-68% 27 success rate," and that "APR has been shown to increase the chances of allowing the pregnancy to 28

continue." As explained above, however, these statements are misleading because no credible
 evidence supports these statements.

92. RealOptions similarly implies that APR is effective for continuing a pregnancy
after a 72-hour window following mifepristone administration. In response to two different
FAQs about timing for APR, RealOptions states that potential patients should nevertheless call
because "[i]t may not be too late," misleadingly implying that APR is effective past the 72-hour
period. This statement is misleading because there is no evidence supporting this statement.

8 93. RealOptions licenses all five of its clinics with the California Department of
9 Health. Dr. Mary Davenport, who is the medical director for two of RealOptions' clinics, was
10 Delgado's co-author for both the 2012 Case Series and the 2018 Report. Davenport
11 acknowledged that the data collected for the 2018 Report was insufficient for its ultimate
12 conclusions.

13

## B. Consent Forms

14 94. In its form to obtain consent for what it calls "pregnancy sustaining progesterone 15 therapy," RealOptions misleadingly omits that APR patients may experience severe bleeding as a 16 result of undergoing the process, even though the 2019 U.C. Davis study found that there was a 17 risk of that outcome. RealOptions instead states that patients may experience "side effects such 18 as pain or swelling at the injection site, an increase in pregnancy/hormone symptoms (breast 19 tenderness, nausea, and/or increased body or facial hair), weight loss, weight gain, acne, loss of 20 scalp hair, drowsiness and/or dizziness." The failure to include the possibility of severe bleeding 21 makes this statement materially misleading, in that patients are likely to believe that the side 22 effects from APR are minor, when in fact they could be life threatening.

- 95. In a June 2020 podcast, Davenport and Delgado spoke about APR, including
  discussing the 2019 U.C. Davis study, thereby demonstrating Davenport's knowledge of that
  study and the potentially life-threatening severe bleeding that resulted.<sup>30</sup> Given her role as a
  RealOptions' medical director, it is appropriate to impute her knowledge to RealOptions.
- <sup>30</sup> (Mises Inst., *Mary Davenport and George Delgado on Reversing Medical Abortion* (June 18, 2020), <u>https://mises.org/library/mary-davenport-and-george-delgado-reversing-medical-abortion</u>.)

1	CAUSES OF ACTION	
2	FIRST CAUSE OF ACTION	
3	(False or Misleading Statements)	
4	(Bus. & Prof. Code, § 17500 et seq.)	
5	96. The People reallege all paragraphs set forth above and incorporate them by	
6	reference as though they were fully set forth in this cause of action.	
7	97. From a date unknown to the People and continuing to the present, Defendants have	
8	engaged in and continue to engage in, aided and abetted and continue to aid and abet, and	
9	conspired to and continue to conspire to engage in acts or practices that constitute violations of	
10	Business and Professions Code section 17500 et seq., by making or causing to be made untrue or	
11	misleading statements with the intent to induce members of the public to undergo APR.	
12	Defendants' untrue and misleading representations include, but are not limited to, the following:	
13	a. that APR can "reverse" a medication abortion, as well as an "effective"	
14	process that "has been shown to increase the chances of allowing the	
15	pregnancy to continue," and that APR has a 64-68% success rate, even	
16	though no credible scientific evidence supports these claims;	
17	b. that APR may be effective after a 72-hour window following	
18	administration of mifepristone by encouraging pregnant people to contact	
19	them "even if more than 72 hours have passed," even though no credible	
20	scientific evidence supports this claim;	
21	c. that the rate of birth defects following APR "is less or equal to the rate in	
22	the general population," even though no credible scientific evidence	
23	supports these claims;	
24	d. that "thousands of lives" have been saved via APR, even though no	
25	credible evidence supports this claim;	
26	e. that APR may be effective following administration of misoprostol and	
27	methotrexate, even though no credible scientific evidence supports this	
28	claim; and	
	26	

1	f. that A	PR can cause only non-life-threatening side effects, when in fact
2	APR can cause severe, life-threatening bleeding.	
3	98. Defendants knew or should have known that these statements were misleading.	
4	SECOND CAUSE OF ACTION	
5	(Unlawi	ful, Unfair, and Fraudulent Business Practices)
6		(Bus. & Prof. Code, § 17200 et seq.)
7	99. The People re	eallege all paragraphs set forth above and incorporate them by
8	reference as though they we	re fully set forth in this cause of action.
9	100. From a date u	inknown to the People and continuing to the present, Defendants have
10	engaged in and continue to engage in, aided and abetted and continue to aid and abet, and	
11	conspired to and continue to conspire to engage in unlawful, unfair, and/or fraudulent acts or	
12	practices, which constitute unfair competition within the meaning of section 17200 of the	
13	Business and Professions Code. Defendants' acts or practices include, but are not limited to, the	
14	following:	
15	a. Violating Business and Professions Code section 17500 et seq., as alleged	
16	in the First Cause of Action;	
17	b. Fraud	ulently representing the following:
18	i.	Via HBI and RealOptions, that APR can "reverse" medication
19		abortions, is an "effective" process that "has been shown to increase
20		the chances of allowing the pregnancy to continue," and that APR
21		has a 64-68% success rate, even though no credible scientific
22		evidence supports these claims;
23	ii.	Via HBI and RealOptions, that APR may be effective after a 72-
24		hour window following administration of mifepristone by
25		encouraging pregnant people to contact them "even if more than 72
26		hours have passed," even though no credible scientific evidence
27		supports this claim;
28	iii.	Via HBI, that the rate of birth defects following APR "is less or
		27

Complaint for Permanent Injunction, Civil Penalties, Abatement, and Other Equitable Relief

1	equal to the rate in the general population," even though no credib	
2	scientific evidence supports this claim;	
3	iv. Via HBI, that "thousands of lives" have been saved via APR, even	
4	though no credible evidence supports that statement;	
5	v. Via HBI, that APR may be effective following administration of	
6	misoprostol or methotrexate, even though no evidence supports this	
7	claim; and	
8	vi. Via RealOptions, that APR can cause only non-life-threatening side	
9	effects and omitting that APR can cause severe, life-threatening	
10	bleeding.	
11	101. Each and every separate act, including, but not limited to: each call to the APR	
12	hotline and each chat initiated on the live chat, each training kit sold to affiliates, and each	
13	consent form provided to pregnant individuals, constitutes an unlawful, unfair, and/or fraudulent	
14	business practice. Each time that the Defendants engaged in each separate unlawful, unfair,	
15	and/or fraudulent act, omission, or practice is a separate and distinct violation of Business and	
16	Professions Code section 17200.	
17	PRAYER FOR RELIEF	
18	WHEREFORE, the People respectfully request that the Court enter judgment in favor of the	
19	People and against Defendants, jointly and severally, as follows:	
20	1. That Defendants, their successors, agents, representatives, employees, assigns, and	
21	all persons who act in concert with Defendants be permanently or preliminarily enjoined from	
22	making any untrue or misleading statements in violation of Business and Professions Code	
23	section 17500, including, but not limited to, the untrue or misleading statements alleged in this	
24	Complaint, under the authority of Business and Professions Code section 17535;	
25	2. That Defendants, their successors, agents, representatives, employees, assigns, and	
26	all persons who act in concert with Defendants be permanently or preliminarily enjoined from	
27	engaging in unfair competition as defined in Business and Professions Code section 17200,	
28	including, but not limited to, the acts and practices alleged in this Complaint, under the authority 28	

1

of Business and Professions Code section 17203;

3. That the Court make such orders or judgments as may be necessary, including
 preliminary injunctive and ancillary relief, to prevent the use or employment by any Defendant of
 any practice which violates Business and Professions Code section 17500, or which may be
 necessary to restore to any person in interest any money or property, real or personal, which may
 have been acquired by means of any such practice, under the authority of Business and
 Professions Code section 17535;

- 4. That the Court make such orders or judgments as may be necessary, including
  preliminary injunctive and ancillary relief, to prevent the use or employment by any Defendant of
  any practice which constitutes unfair competition or as may be necessary to restore to any person
  in interest any money or property, real or personal, which may have been acquired by means of
  such unfair competition, under the authority of Business and Professions Code section 17203;
- 5. That the Court assess a civil penalty of up to \$2,500 against each Defendant for
  each violation of Business and Professions Code section 17500, in an amount according to proof,
  under the authority of Business and Professions Code section 17536;

6. That the Court assess a civil penalty of up to \$2,500 against each Defendant for
each violation of Business and Professions Code section 17200, in an amount according to proof,
under the authority of Business and Professions Code section 17206;

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That the People recover their costs of suit;

8. That the People receive all other relief to which they are legally entitled; and
That the Court award such other relief that it deems just, proper, and equitable.

1	Dated: September 21, 2023	Respectfully submitted,
2		ROB BONTA
3		Attorney General of California RENU GEORGE
4		Senior Assistant Attorney General Karlı Eisenberg Kathleen Boergers
5		Supervising Deputy Attorneys General
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8		Erica Connolly Hayley Penan
9 10		Deputy Attorneys General Attorneys for Defendant Rob Bonta, in his official capacity as Attorney General of the State of California
10		State of California
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