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REGULATION OF ENCAPSULATED PLACENTA

Greer Donley

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REGULATION OF ENCAPSULATED PLACENTA

GREER DONLEY*

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The practice of placenta encapsulation is rapidly growing. It typically involves post-partum mothers consuming their placentas as pills in the months after childbirth. The perceived benefits include improved mood and energy, reduced bleeding and pain, and greater milk supply. But these effects are unproven, and consumption comes

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with health risks. The rise of this trend has sparked a vigorous debate in the recent medical literature, but this Article is the first to consider the legal implications of placenta encapsulation. This Article examines whether FDA should regulate encapsulated placenta, and if so, whether it should be regulated as a drug, supplement, or human tissue. Because the product does not fit neatly into any of FDA's predetermined categories, the Article explores the optimal regulatory categorization from a policy and gender perspective. It concludes that FDA should regulate encapsulated placenta as both a supplement and particular type of low-risk human tissue. The regulations associated with these categories will sufficiently protect women without creating such high entry barriers that the product would effectively (and paternalistically) disappear from the market.

INTRODUCTION

A trend has emerged among new mothers: post-partum placenta consumption. This practice typically involves a provider collecting a woman's placenta from the hospital or home after the child is born, then dehydrating, grinding, and encapsulating the organ so that the post-partum mother can ingest it as pills in the months following her child's birth. The practice is called placentophagy, and though it may seem like a fringe movement, it is becoming increasingly common, especially after numerous celebrities publicly discussed their experiences with it. Small placentophagy shops, which are generally owned and operated by women, have opened all over the United States. The majority of hospitals now have policies to facilitate the process, and some states have enacted statutes to protect a woman's right to her placenta.¹ This new trend has caused a vigorous debate in the medical literature,² but this Article is the first to explore the legal implications of placenta encapsulation.

Despite the recent popularity, the United States Food and Drug Administration ("FDA") does not currently regulate encapsulated placenta. Proponents of placentophagy believe that it fights post-partum depression, replaces vitamins that were depleted in the childbirth process, and reduces post-partum bleeding and pain. Opponents, however, respond that there is little to no research supporting the purported health benefits of encapsulated placenta and that the product may contain toxins or carry risks associated with

1. Sixty-one percent of hospitals have a policy that allows for the release of placentas. Rebecca N. Baergen, Harshwardhan M. Thaker & Debra S. Heller, *Placental Release or Disposal? Experiences of Perinatal Pathologists*, 16 PEDIATRIC & DEVELOPMENTAL PATHOLOGY 327, 327–28 (2015).

2. See e.g., Baergen et al., *supra* note 1, at 327; Cynthia W. Coyle et al., *Placentophagy: Therapeutic Miracle or Myth?*, 18 ARCHIVES WOMEN'S MENTAL HEALTH 673 (2015); Alex Farr et al., *Human Placentophagy: A Review*, 218 AM. J. OBSTETRICS & GYNECOLOGY 401 (2017); Laura K. Gryder et al., *Effects of Human Maternal Placentophagy on Maternal Postpartum Iron Status: A Randomized, Double-Blind, Placebo-Controlled Pilot Study*, 62 J. MIDWIFERY & WOMEN'S HEALTH 68 (2017); Emily H. Hayes, *Consumption of the Placenta in the Postpartum Period*, 45 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 78 (2016); Rachel Joseph et al., *A Literature Review on the Practice of Placentophagia*, 20 NURSING FOR WOMEN'S HEALTH 476 (2016); Marisa Marraccini & Kathleen S. Gorman, *Exploring Placentophagy in Humans: Problems and Recommendations*, 60 J. MIDWIFERY & WOMEN'S HEALTH 371 (2015); Stephanie A. Schuette et al., *Perspectives from Patients and Healthcare Providers on the Practice of Maternal Placentophagy*, 23 J. ALTERNATIVE & COMPLEMENTARY MED. 60 (2017); Sharon M. Young et al., *Placentophagy's Effects on Mood, Bonding, and Fatigue: A Pilot Trial, Part 2*, 31 WOMEN & BIRTH e258 (2017) [hereinafter Young, *Pilot 2*].

consumption. These possible harms, opponents argue, underscore the need for regulation, especially now that the practice is growing and the risks are becoming clearer. But placentophagy advocates are skeptical of regulation, fearing that small placentophagy providers—almost all of whom are women—cannot afford to comply with onerous regulatory burdens; as a result, if FDA regulated the product too harshly, providers would likely go out of business, and their product would disappear with them.

FDA regulation always involves trade-offs—it can both protect individuals from harm, while also impairing the public's access to beneficial products. Balancing these concerns is particularly complicated around pregnancy and childbirth as it necessarily invokes criticisms on the state's overregulation of women's bodies. But the dilemma with encapsulated placenta goes beyond gender: it also involves questions surrounding the agency's statutory framework. FDA's regulatory scheme centers around categories; for example, drugs are regulated differently (and more stringently) than foods or supplements. So even if FDA were to conclude that regulation of encapsulated placenta is warranted, under which category should FDA regulate it? Encapsulated placenta could arguably meet the definition of a drug, human tissue, or supplement—categories with vastly different regulations.

This Article explores if and how FDA should regulate encapsulated placenta. In Part I, I provide background on placentophagy, discussing the motivations underlying women's decisions to purchase encapsulated placenta, the purported benefits and risks of consumption, and the published research studying its effects. In Part II, I review FDA's category-based regulatory scheme for drugs, supplements, and human tissues. I explain the definition and regulations associated with each categorization. Because encapsulated placenta could meet the definition of three product categories, I refer to it as a mixed product—a term I use to describe products that fall within the definitions of numerous FDA categories. This Part concludes with a description of how FDA typically sorts mixed products, finding that the agency has never addressed how to categorize a product like encapsulated placenta.

In light of this ambiguity, I argue in Part III that two policy concerns should be considered when deciding whether and how to regulate encapsulated placenta. First, I explore the constant tension in all FDA regulation: the need to balance consumer access to health-related goods against consumer protection from unsafe or ineffective products. Second, I highlight the centrality of gender to the debate, looking to other examples of regulation in the pregnancy and

childbirth context, which often overprotect women to their detriment. I note that most consumers of encapsulated placenta see themselves as rejecting a patriarchal medicalization of childbirth that has not benefited them, and that overregulating the product would perpetuate their perception that female autonomy over reproductive decision making is not being respected. I conclude that although a regulatory floor is necessary to ensure safe consumption of the product, encapsulated placenta should not be regulated so harshly that women lose access to a safe product that they perceive as beneficial. Women deserve protection without paternalism.

Finally, in Part IV, I explain why FDA's traditional approach to categorizing mixed products would lead to a bad policy result with encapsulated placenta: it would either remove access to the product entirely or fail to provide adequate protection. Instead, I argue that FDA should use its discretion (as it has done with similar products) to narrowly tailor the regulation of encapsulated placenta to cover only the product's genuine risks. The main types of harms that encapsulated placenta risks are (1) the spread of communicable diseases resulting from improperly handled tissue and (2) the public's deception when manufacturers claim without proof that their product will cure, mitigate, or prevent disease. These harms can be prevented by regulating encapsulated placenta as both a supplement and particular kind of human tissue, designated as a 361 HCT/P—products with regulations designed to prevent those exact risks. These regulations, however, would not require premarket review or proof of efficacy: two barriers that would keep encapsulated placenta off the market if it were regulated as a drug. Regulating encapsulated placenta in this narrowly tailored way would provide the regulatory floor necessary to protect women without resorting to overprotection.

I. PLACENTOPHAGY PREVALENCE, MOTIVATIONS, AND RISKS

The placenta is a vascularized organ that connects the mother to the fetus through the umbilical cord.³ It delivers oxygen, nutrients, and hormones to the fetus and acts as a barrier to protect the fetus from toxins.⁴ Almost immediately after a baby is born, the placenta is delivered. It typically becomes medical waste,⁵ though many new uses have emerged, including most significantly, as an ingredient for stem

3. Schuette et al., *supra* note 2, at 60.

4. *Id.*

5. Baergen et al., *supra* note 1, at 327.

cell research.⁶ With the promise of new stem cell treatments, women can even bank their placentas for their own future use (or the use of a family member) under the theory that genetically matching stem cells may be effective at treating their own diseases in the future.⁷

This Article examines a particular new use for the placenta: post-partum maternal consumption through placentophagy. Placentophagy started to grow in popularity over the past two decades and is now fairly commonplace, particularly among white, middle class women.⁸ Although there are no national estimates, in Portland, Oregon alone, approximately 2,000 women per year consume their placentas.⁹ A long list of celebrities, including Kim Kardashian and January Jones, have blogged and written about their experiences with placentophagy.¹⁰ Respected periodicals are discussing and debating the practice.¹¹ *The Washington Post*, for instance, reported on the

6. Anne O. Glausser, *The Placenta's Second Life 2* (June 9, 2009) (unpublished master's thesis, Massachusetts Institute of Technology) (available at <https://dspace.mit.edu/bitstream/handle/1721.1/54572/567779304-MIT.pdf?sequence=2>) (“[E]xpelled placenta is used in eye surgery, in training dogs to sniff dead bodies, in toxicology research, in forensics, in cosmetics, and, most significantly, in an emerging field of stem cell research.”).

7. *Why Bank?*, AMERICORD, <https://www.americordblood.com/banking/placenta-tissue/> (last visited Mar. 25, 2019).

8. See, e.g., Joseph et al., *supra* note 2 at 480 (“[T]his practice is particularly acceptable among educated, married (90%), middle-class White American women (93%; N = 189).”); Jodi Selander et al., *Human Maternal Placentophagy: A Survey of Self-Reported Motivations and Experiences Associated with Placenta Consumption*, 52 *ECOLOGY FOOD & NUTRITION* 93, 107–08 (2013); Schuette et al., *supra* note 2, at 62–63.

9. Sharon M. Young et al., *Presence and Concentration of 17 Hormones in Human Placenta Processed for Encapsulation and Consumption*, 43 *PLACENTA* 86, 86 (2016) [hereinafter Young, *17 Hormones in Human Placenta*].

10. Sarah Bunton, *11 Celebrities Who Ate Their Placenta & Are Happy to Admit It*, ROMPER (July 6, 2016), <https://www.romper.com/p/11-celebrities-who-ate-their-placenta-are-happy-to-admit-it-13659>; Mikaela Conley, *Mad Mom? January Jones Eats Her Own Placenta*, ABC NEWS (Mar. 26, 2012), <http://abcnews.go.com/blogs/health/2012/03/26/mad-mom-january-jones-eats-her-own-placenta/>; Jamieson Cox, *Kim Kardashian's Placenta Convinced Me to Subscribe to Her App*, VERGE (Dec. 14, 2015, 4:50 PM), <https://www.theverge.com/2015/12/14/10123898/kim-kardashian-app-subscription-eating-placenta>.

11. Tara Haelle, *Placenta Pills Gain Fans Among New Moms, but Benefits Are Elusive*, NPR (June 4, 2015), <http://www.npr.org/sections/health-shots/2015/06/04/411990944/placenta-pills-gain-fans-among-new-moms-but-benefits-are-elusive>; Peter Holley, *Her Newborn Kept Getting Sick Because She Was Ingesting Placenta*, CDC SAYS, WASH. POST (June 30, 2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/06/30/her-newborn-kept-getting-sick-because-she-was-ingesting-placenta-cdc-says/?utm_term=.b8906809d120; Ellen McCarthy, *'Are You Going to Eat That?' When It Comes to Placenta, the Answer Is Increasingly 'Yes'*, WASH. POST (Aug. 5, 2014), <https://www.washingtonpost.com/lifestyle/style/are-you-going-to-eat>

“dramatic rise in women choosing to ingest their placentas after giving birth,”¹² and has called placentophagy “mainstream in recent years.”¹³

A study published in the *Journal of Alternative and Complementary Medicine* found that two-thirds of female patients were familiar with placentophagy, as were 89% of providers.¹⁴ Twenty percent of the surveyed patients knew someone who had consumed her placenta.¹⁵ Women with a household income greater than \$100,000 and with higher education were more likely to have heard of placentophagy and be willing to try it.¹⁶ A similar study of both male and female college students also found that two-thirds of participants knew about placentophagy and more than 25% would consider it themselves.¹⁷ The practice is now so commonplace that 66% of hospitals have protocols in place allowing the placenta’s release from the hospital.¹⁸ Some states, like Hawaii, Oregon, Texas, and Massachusetts, have created a statutory right to the placenta after birth.¹⁹ And in Mississippi, a woman successfully sued to have the

that-when-it-comes-to-placenta-the-answer-is-increasingly-yes/2014/08/05/0022c596-180b-11e4-9e3b-7f2f110c6265_story.html?utm_term=.9041f92a8655; Nancy Redd, *I Regret Eating My Placenta*, N.Y. TIMES (Mar. 25, 2012, 9:13 PM), <https://parenting.blogs.nytimes.com/2012/03/25/i-regret-eating-my-placenta/>; Olga Oksman, *Eating Your Placenta—Is It Healthy or Just Weird?*, GUARDIAN (Feb. 10, 2016, 14:05 EST), <https://www.theguardian.com/lifeandstyle/2016/feb/10/eating-your-placenta-healthy-motherhood-new-mothers-infants-postpartum-depression-placentophagy-fda>.

12. McCarthy, *supra* note 11.

13. Holley, *supra* note 11.

14. Schuette et al., *supra* note 2, at 60. The study surveyed women at two women’s health practices in Chicago and healthcare providers operating out of hospitals in three different urban settings.

15. *Id.* at 62.

16. *Id.*

17. Gwendolyn E. Cremers & Kathryn G. Low, *Attitudes Toward Placentophagy: A Brief Report*, 35 HEALTH CARE FOR WOMEN INT’L 113, 117 (2014).

18. In one study, 66.7% of hospitals had a policy for the release of placentas from the institution. Baergen et al., *supra* note 1, at 327–28; *see also* Hayes, *supra* note 2, at 86; Joseph et al., *supra* note 2, at 481; McCarthy, *supra* note 11 (“Katherine Himes, a doctor of maternal fetal medicine at the University of Pittsburgh Medical Center, has had so many patients come to her with questions about placentas that the hospital developed a protocol for those who wish to take their placentas home.”); Schuette et al., *supra* note 2, at 63.

19. *See, e.g.*, Hayes, *supra* note 2, at 86 (“Laws regulating infectious waste in Hawaii, Oregon, and most recently Texas explicitly allow mothers to take their placentas home from the hospital” and “[i]nfectious waste handling and disposal laws in other states neither allow nor prohibit women from taking their placentas home”); Memorandum from Lauren Smith, Medical Director and Chief Medical

placenta removed from the state's list of medical waste that was not permitted to leave the hospital.²⁰ Mississippi now "legalizes placental release upon request."²¹

Placentophagy can take many forms. Some women cook and eat the placenta like meat, while others mix it raw into smoothies or other edibles.²² The vast majority of women, however, pay placentophagy providers to pick up the placenta from the hospital, dehydrate it, grind it, and place it into capsules that can be swallowed as pills during their first month's post-partum.²³ The placenta is typically heated during processing to kill any bacteria that may be on the organ.²⁴ Placentophagy providers can process the placenta at their own homes,²⁵ at a processing site,²⁶ or at the mother's house.²⁷ The price of the service often includes other placenta-based products, such as placenta tinctures—raw placenta steeped in alcohol—placenta soaps, and placenta lotions.²⁸ The average cost is between \$150 and \$200.²⁹

Almost all placentophagy providers are women, working either as sole practitioners or in collaboration with other women.³⁰ Many providers have been consumers themselves and were motivated to start their businesses to help other mothers experience the same

Officer, to Hospital CEOs (Oct. 25, 2010), available at <http://www.mass.gov/eohhs/docs/dph/environmental/sanitation/placenta-guidance.pdf>.

20. Farr et al., *supra* note 2, at 407.

21. *Id.*

22. Coyle et al., *supra* note 2, at 674–75; Joseph et al., *supra* note 2, at 478; McCarthy, *supra* note 11.

23. In one survey, between 70–80% of women chose encapsulation. Hayes, *supra* note 2, at 80.

24. Selander et al., *supra* note 8, at 95.

25. See *Questions to Ask Before Hiring Your Placenta Encapsulation Specialist*, FIND PLACENTA ENCAPSULATION, <http://findplacentaencapsulation.com/questions-to-ask-before-hiring-your-placenta-encapsulation-specialist/> (last visited Mar. 25, 2019) ("Some specialists . . . prepare the placenta in their home kitchen.").

26. See, e.g., *Services*, PLACENTA ENCAPSULATION KC, <http://www.placentaencapsulationkc.com/services> (last visited Mar. 25, 2019).

27. See, e.g., *The Placenta Lady Experience*, PLACENTA LADY, <http://www.placentlady.com/experience> (last visited Mar. 25, 2019).

28. See, e.g., *Services*, *supra* note 26; *Valerie Rosas and Henry Garcia*, FIND PLACENTA ENCAPSULATION, <http://findplacentaencapsulation.com/placenta-specialist-directory/valerie-rosas/> (last visited Mar. 25, 2019).

29. See, e.g., Joseph et al., *supra* note 2, at 481–82.

30. Almost all of the 748 placentophagy providers listed on the Placenta Encapsulation website are women. *Find a Placenta Specialist*, FIND PLACENTA ENCAPSULATION, <http://findplacentaencapsulation.com/find-a-placenta-specialist/> (last visited Mar. 25, 2019).

benefits they experienced.³¹ As a result, women are almost exclusively the providers and consumers of placentophagy.

Women engage in placentophagy for a variety of perceived benefits. First among them is the belief that consuming one's placenta will combat the onset of symptoms of post-partum depression or the less severe "baby blues."³² Fifty percent of placentophagy users were motivated to purchase encapsulated placenta because they had previously experienced a postnatal mood disorder after at least one of their former pregnancies.³³ Other women consume their placentas seeking to increase their breast milk supply, reduce post-partum pain or bleeding, improve energy, or replenish depleted nutrients and hormones.³⁴ For many, placentophagy is a rejection of what they perceive as the "patriarchal medicalization of birth that has given medicine power over women's bodies."³⁵ Instead, these women typically gravitate toward a female-centered birthing approach that treats childbirth as empowering.³⁶

The anecdotal evidence is overwhelmingly positive. The only published study to survey placentophagy users found that 95% of women who had engaged in placentophagy had a positive experience and 98% stated that they would do it again for subsequent births.³⁷ More specifically, 40% of women reported feeling an improved mood, 26% reported increased energy, 15% reported improved lactation, and 7% reported alleviated bleeding.³⁸

It is not difficult to understand why the practice has grown in popularity. A woman's first months post-partum are often filled with physical pain and emotional tumult—women report feeling breast, vaginal, or cesarean pain, urinary incontinence, hemorrhoids, hair

31. See, e.g., *Amelia Rebolo*, FIND PLACENTA ENCAPSULATION, <http://findplacentaencapsulation.com/placenta-specialist-directory/amelia-rebolo/> (last visited Mar. 25, 2019).

32. Schuette et al., *supra* note 2, at 64 ("Perhaps our most significant finding was that mothers with a history of a postpartum mood disorder were more willing to try placentophagy in place of prescription medication than women with no prior mental health issues."); Selander et al., *supra* note 8, at 102–03;

33. Selander et al., *supra* note 8, at 102.

34. *Id.*

35. Elizabeth Dickinson, et al., *Empowering Disgust: Redefining Alternative Postpartum Placenta Practices*, 40 WOMEN'S STUD. COMM. 111, 123 (2017); see also Section III.A.

36. Dickinson et al., *supra* note 35, at 124.

37. Selander et al., *supra* note 8, at 105. *But see* Redd, *supra* note 11.

38. Selander et al., *supra* note 8, at 105.

loss, anxiety, and severe mood swings.³⁹ Twenty percent of women experience post-partum depression⁴⁰ and up to 80% suffer from a short-term, less severe post-partum mood disorder colloquially referred to as the baby blues.⁴¹ Women frequently feel disappointed that their physicians did not prepare them for these post-partum symptoms, focusing instead on pregnancy and birth.⁴² Furthermore, these symptoms come at a time when women are no longer in as regular contact with their healthcare providers.⁴³ And “[p]roviders are often hesitant to prescribe medication to breast-feeding women because of concerns regarding untoward effects on the infant.”⁴⁴ Also out of concern for their breastfeeding infants, “postpartum women are more likely to prefer nonpharmacologic treatment methods for depression.”⁴⁵ As a result, when women are facing the real and challenging struggles after giving birth, they may also lack continuity of care and feel personal or external pressure to avoid pharmaceuticals that might improve their physical or emotional symptoms. Placentophagy gives women a mechanism to improve these symptoms without the barriers existing in the medical system or the concerns associated with pharmaceuticals, whether or not those concerns are warranted.⁴⁶

Despite the perceived benefits of placentophagy, there is very little scientific evidence demonstrating the health effects that women anecdotally experience. Scientific theories exist to explain the perceived benefits,⁴⁷ and research in animals has demonstrated that

39. Elizabeth A. Howell, *Lack of Patient Preparation for the Postpartum Period and Patients' Satisfaction with Their Obstetric Clinicians*, 115 *OBSTETRICS & GYNECOLOGY* 284, 285 (2010).

40. Schuette et al., *supra* note 2, at 61.

41. The baby blues are a less severe, short-term form of post-partum depression. *Baby Blues*, AM. PREGNANCY ASS'N, <http://americanpregnancy.org/first-year-of-life/baby-blues/> (last updated Aug. 2015).

42. Anika Martin et al., *Views of Women and Clinicians on Postpartum Preparation and Recovery*, 18 *MATERNAL CHILD HEALTH J.* 707, 709–10 (2014); *Baby Blues*, *supra* note 41.

43. Martin et al., *supra* note 42, at 710.

44. Schuette et al., *supra* note 2, at 61.

45. *Id.*

46. The recommendation to avoid drugs during pregnancy and lactation may not always be in the best interest of the mother or the child and can reflect the government or provider's preference to protect the child from unknown risks over the mother's known pain. *See, e.g.*, Greer Donley, *Encouraging Maternal Sacrifice: How Regulations Governing the Consumption of Pharmaceuticals During Pregnancy Prioritize Fetal Safety over Maternal Health and Autonomy*, 39 *N.Y.U. REV. L. & SOC. CHANGE* 45, 47 (2015).

47. *See, e.g.*, Joseph et al., *supra* note 2, at 479–80; Marraccini & Gorman, *supra* note 2 at 375–76.

consumed placenta may be effective at reducing pain, increasing lactation, and replenishing hormones in animals, though it is unclear whether this data can be extrapolated to humans.⁴⁸ Supporters also point to the fact that nearly all mammals eat their placenta,⁴⁹ and that Chinese medicine has treated various disorders with dried human placenta for centuries.⁵⁰

But studies in humans have not demonstrated benefits.⁵¹ For instance, one theory to explain the placenta's positive effect is that it replaces key nutrients and hormones that were depleted during the birthing process.⁵² But one study that analyzed the nutrients in a daily dosage of encapsulated placenta found that it only contained 25% of the daily-recommended iron intake for lactating women.⁵³ Other nutrients were even less prominent.⁵⁴ Another study analyzing the concentrations of hormones in encapsulated placenta found that only three of seventeen hormones were concentrated enough to have even the possibility of a therapeutic effect.⁵⁵ When a double-blind, placebo-controlled trial evaluated the salivary hormone concentrations of post-partum women who consumed their placentas versus placebo, it found no statistically significant difference.⁵⁶ The same trial found no statistically significant difference in depressive symptoms between those women who ingested placebo and those who ingested placenta over the entire post-partum period, though it did report preliminary findings that the placenta group was less fatigued and had less depressive symptoms in the first week post-partum.⁵⁷ Finally, a placebo-controlled study found that encapsulated placenta did not improve post-partum iron status as compared to a placebo of dehydrated beef, despite containing higher concentrations of iron.⁵⁸ Taken together, the evidence suggests that the benefits of

48. Coyle et al., *supra* note 2, at 675–77.

49. Hayes, *supra* note 2, at 79; Marraccini & Gorman, *supra* note 2 at 372.

50. Coyle et al., *supra* note 2, at 674.

51. *Id.* (“Despite the amount of information available to the public on the therapeutic benefits of placentophagy, there is no scientific evidence examining its effects in humans, and the data from animals are inconclusive.”).

52. Marraccini & Gorman, *supra* note 2, at 375–76.

53. Sharon M. Young et al., *Human Placenta Processed for Encapsulation Contains Modest Concentrations of 14 Trace Minerals and Elements*, 36 NUTRITION RES. 872, 876 (2016) [hereinafter Young, *14 Trace Minerals*].

54. *Id.* at 877.

55. Young, *17 Hormones in Human Placenta*, *supra* note 9, at 88–89.

56. Sharon M. Young et al., *Effects of Placentophagy on Maternal Salivary Hormones: A Pilot Trial, Part 1*, 31 WOMEN & BIRTH e245, e245 (2017) [hereinafter Young, *Pilot 1*].

57. Young, *Pilot 2*, *supra* note 2, at 258.

58. Gryder et al., *supra* note 2, at 74, 77.

placentophagy may be largely attributed to the placebo effect.⁵⁹ Of course, the placebo effect can be very powerful, causing improvements on its own,⁶⁰ and some women still advocate for access to placenta pills even under the assumption that the benefits derive primarily from placebo.⁶¹

The unclear benefits of placentophagy must be balanced against possible risks. One initial concern is that women with serious depression might forgo needed anti-depressants and face a mental health crisis if placentophagy is not effective.⁶² Opponents also raise concerns about the safety of the practice even among relatively healthy mothers. For instance, because the placenta functions to filter out toxins, some have theorized that those toxins could be present in encapsulated placenta and harmful to consume.⁶³ Another risk is the potential adverse effect of bacteria or viruses that grow on the placental tissue when it is not properly handled.⁶⁴ This concern is especially prominent in light of an announcement by the Centers for Disease Control reporting that an infant contracted a bacterial infection that was passed through its mother's breast milk after she consumed encapsulated placenta.⁶⁵ The infant was hospitalized twice before the cause of the infection was discovered.⁶⁶ Opponents are also concerned with the transmission of disease if multiple placentas are processed at the same site without proper sanitation procedures. Even worse, placentophagy providers can intentionally cross-contaminate a woman's pills. One egregious example of this occurred in 2008 when FDA raided a placentophagy site in Miami that was accused of making large batches of placenta pills by mixing as many as fifteen

59. Coyle et al., *supra* note 2, at 678 ("Reports of human benefit may, at least partially, be a result of placebo effects . . .").

60. *The Power of the Placebo Effect*, HARV. HEALTH PUB. (May 2017), <https://www.health.harvard.edu/mental-health/the-power-of-the-placebo-effect>.

61. Dickinson et al., *supra* note 35, at 122 (quoting a supporter as articulating the following sentiment: "Even if it is a placebo effect, placebo is powerful. If it can possibly help, I don't have a problem trying it. Let's give it a shot." And noting that "the lack of medical research [here] is not an issue. If it 'can't hurt,' and if it may just help, supporters make a leap of faith to try.").

62. See generally Nicholas Bakalar, *Science Fails to See Benefits of Eating Placenta*, N.Y. TIMES (June 9, 2015, 1:33 PM), https://well.blogs.nytimes.com/2015/06/09/science-fails-to-see-benefits-of-eating-placenta/?_r=1.

63. Coyle et al., *supra* note 2, at 674.

64. *Id.*

65. Genevieve L. Buser et al., Notes from the Field: *Late-Onset Infant Group B Streptococcus Infection Associated with Maternal Consumption of Capsules Containing Dehydrated Placenta—Oregon, 2016*, CENTERS FOR DISEASE CONTROL & PREVENTION 677 (June 30, 2017), <https://www.cdc.gov/mmwr/volumes/66/wr/mm6625a4.htm>.

66. *Id.*

placentas together without telling the mothers that their placenta pills contained other women's placentas.⁶⁷

These concerns are well taken, but largely focus on the risks associated with bad practices. There is little to no evidence that encapsulated placenta is unsafe when processed properly. One study explored the theory that the placenta may contain toxins that are harmful to consume; it found that, to the extent that any toxins were present, their concentrations were negligible and did not render the placenta unsafe.⁶⁸ Another study found that although "[p]otentially pathogenic organisms (*E. coli*, *Gardnerella vaginalis*) were detected in raw placental tissue[, they] were absent after dehydration," which exposes the placenta to high heat.⁶⁹ It also confirmed that dehydrated placenta lacked any toxic elements.⁷⁰ With regard to the CDC report, placentophagy advocates were quick to highlight that CDC's description of how the placenta was prepared made clear that the provider did not properly cook and dehydrate the tissue to kill bacteria.⁷¹ Some researchers, including the CDC's own report, have supported this hypothesis, while others have argued that even if poor practices were not to blame, one case study should not outweigh strong evidence of safety elsewhere.⁷² Many placentophagy providers

67. *Florida Department of Health Joint Investigation Leads to Federal Search Warrant in Miami*, WCTV (Dec. 31, 2008, 3:55 PM), <http://www.wctv.tv/home/headlines/36945319.html> [hereinafter *Florida Department of Health*].

68. Young, *14 Trace Minerals*, *supra* note 53, at 877. The study was careful to note that an individual mother's exposure to toxins—for instance, a woman who smoked during her pregnancy—may cause her specific placenta to contain more contaminants than the placentas the study examined. *Id.* at 873.

69. Sophia K. Johnson et al., *Human Placentophagy: Effects of Dehydration and Steaming on Hormones, Metals and Bacteria in Placental Tissue*, 67 *PLACENTA* 8, 11 (2018).

70. *Id.* at 8 ("According to regulations of the European Union the concentrations of potentially toxic elements (As, Cd, Hg, Pb) were below the toxicity threshold for foodstuffs.").

71. See, e.g., Jodi Selander, *Can I Get Group B Strep from Placenta Capsules?*, *PLACENTA BENEFITS* (June 29, 2017), <https://placentabenefits.info/group-b-strep-from-placenta-capsules/> ("Per the article, heating at 130°F (54°C) for 121 minutes is required to reduce bacteria present in the placental tissue. That did not happen in this case."); *Is Encapsulation Ok When I Am GBS+?*, *ST. LOUIS PLACENTA LADY*, <https://stlplacentalady.weebly.com/what-about-gbs.html> (last visited Mar. 25, 2019) ("It is suspected that the family in Portland, OR, did not prepare their placenta at temperatures high enough to kill the strep bacteria and possibly passed on infection from their capsules to the baby.").

72. Daniel C. Benyshek et al., *Reply Letter to the Editor, Placentophagy Among Women Planning Community Births in the United States: Frequency, Rationale, and Associated Neonatal Outcomes*, *BIRTH* (2018), <https://onlinelibrary.wiley.com/doi/full/10.1111/birt.12381> ("Epidemiology best practices would suggest that a single case study is insufficient evidence from which to extend a clinical recommendation. . .

have themselves created manuals, guidelines, and even certification programs, which describe proper processing procedures designed to specifically prevent incidents like this one.⁷³ The certification programs, for instance, include required trainings on proper food handling and blood-borne pathogens.⁷⁴ Placentophagy studies involving human subjects have not reported any adverse events among the participants,⁷⁵ and the use of dried human placenta in Chinese medicine supports a history of safe use.⁷⁶ Research has also demonstrated that the babies of women who consume their placentas do not fare any worse than those of women who do not.⁷⁷

Furthermore, regulation could mitigate many of the risks associated with bad practices and lead to a safer product. But FDA has thus far “adopted a hands-off policy.”⁷⁸ This might be, at least in part, due to the difficulty in classifying the product under one of FDA’s categories. For instance, one placentophagy provider documented her experience contacting FDA about the regulatory requirements for her

. . . On the contrary, our medical records–based study of more than 7000 placenta consumers, with a control group of over 10 000 non-consumers, found no evidence of harm to the neonate.”); Farr et al., *supra* note 2, at 405 (“The CDC hypothesized that heating for a sufficient time at a temperature adequate to decrease GBS bacterial counts might not have been carried out in this case. Their idea is supported by studies that report the presence of a unique low-abundance microbiome in the healthy human placenta.”).

73. Hayes, *supra* note 2, at 83.

74. See e.g., *Get Certified*, ASS’N PLACENTA PREPARATION ARTS, <https://placentaassociation.com/placenta-certification/> (last visited Mar. 25, 2019); *Placenta Encapsulation Training*, INT’L PLACENTA & POST-PARTUM ASS’N, <https://www.ippatraining.com/placenta-encapsulation> (last visited Mar. 25, 2019).

75. Gryder et al., *supra* note 2, at 68; Selander et al., *supra* note 8, at 109; Young, *Pilot 1*, *supra* note 56, at e255; Young, *Pilot 2*, *supra* note 2, at e267–68. In fact, the only participant to drop out due to an adverse event in Sharon Young’s pilot trial was a subject assigned to the placebo group. Young, *Pilot 1*, *supra* note 56, at e249.

76. Coyle et al., *supra* note 2, at 674.

77. Daniel C. Benyshek et al., *Placentophagy Among Women Planning Community Births in the United States: Frequency, Rationale, and Associated Neonatal Outcomes*, 45 BIRTH 459, 466 (2018), <https://onlinelibrary.wiley.com/doi/abs/10.1111/birt.12375>. Alex Farr and colleagues criticized the scientific methods used in the study in a letter to the editor, to which the research team responded. Alex Farr et al., *Letter to the Editor, Placentophagy Among Women Planning Community Births in the United States: Frequency, Rationale, and Associated Neonatal Outcomes*, BIRTH (2018), <https://onlinelibrary.wiley.com/doi/epdf/10.1111/birt.12375>.

78. Michael McLaughlin, *Placenta Pill Makers Turn Afterbirth into Nutritional Supplement for New Moms*, HUFFPOST (July 20, 2011, 7:54 AM), https://www.huffingtonpost.com/2011/07/20/placenta-pill-maker-nutritional-supplement_n_886420.html.

product.⁷⁹ She described being “passed from one department to another.”⁸⁰ Eventually, FDA told her that because she was “working with human tissue, [her] activities would have to be regulated by the FDA.”⁸¹ This suggests that FDA concluded that the product should be regulated as a human tissue, but FDA never followed up with the provider directly to give guidance. And to the contrary, it later told *USA Today* that the provider’s website contained unsubstantiated disease claims—an indication that FDA considered her product a supplement, not a human tissue.⁸² FDA has thus far never instigated a warning letter or enforcement action against an encapsulated placenta provider, nor has it provided any official guidance on the practice.

FDA’s hands-off approach has left the practice largely unregulated by the federal government; states, too, provide little guidance.⁸³ As the practice grows and the risks of improper processing are exposed, the agency must consider whether and how to regulate encapsulated placenta.⁸⁴ Part II explores the different categories

79. Jodi Selander, *FDA Regulation*, PLACENTA BENEFITS (Aug. 29, 2007), <http://placentabenefits.info/fda-regulation/>.

80. *Id.*

81. *Id.*

82. *Id.*; Steve Friess, *Ingesting the Placenta: Is it Healthy for New Moms?*, USA TODAY (July 24, 2007), <https://www.buffalo.edu/content/dam/www/news/imported/pdf/July07/USATodayKristalPlacenta.pdf>.

83. Bakalar, *supra* note 62 (“This is an unregulated practice with no evidence-based research about its risks and benefits.”); Farr et al., *supra* note 2, at 406 (“Most states in the United States lack clear regulations and safety guidelines that address placentophagy. As a result, current health policy at the state level appears to allow placental release and consumption, under the general rule that what is not explicitly prohibited is permitted.”); Marla Paul, *Eating the Placenta: Trendy but No Proven Health Benefits and Unknown Risks*, NORTHWESTERN NEWS (June 4, 2015), <https://news.northwestern.edu/stories/2015/06/eating-the-placenta-trendy-but-no-proven-health-benefits-and-unknown-risks--> (“There are no regulations as to how the placenta is stored and prepared, and the dosing is inconsistent,” Coyle said. “Women really don’t know what they are ingesting.”). This Article concerns FDA regulation of encapsulated placenta; state regulation is beyond its scope.

84. This analysis will require FDA to contemplate whether state regulation, to the extent it exists at all, is sufficient to protect women. Certain states have laws that may apply to placentophagy. In New York, individuals that work with human tissues must get a license. See McLaughlin, *supra* note 78. But a New York Health Department official stated that no placentophagy provider has ever applied for a license. *Id.* This is despite the fact that numerous placentophagy providers operate in the state and are unaware of the regulations. *Id.*; see also *Placenta Service Provider Directory*, New York, AVOID BABY BLUES, <http://www.avoidthebabyblues.com/new-york.html> (last visited Mar. 25, 2019). The Southern Nevada Health District will not license any facility to process placenta for human consumption, which is why placentophagy providers in the state typically work in the mother’s kitchen.

under which encapsulated placenta could be regulated, providing the background landscape that underlies FDA's regulatory decisions. It explains how encapsulated placenta could meet the definition of a drug, supplement, or human tissue, as well as the general regulatory requirements that manufacturers within each category must meet. Although FDA has a mechanism for sorting products that meet multiple definitions, I explain below that its approach might not provide a clear result in this context.

II. ENCAPSULATED PLACENTA: DRUG, SUPPLEMENT, OR HUMAN TISSUE?

FDA is responsible for “protecting the public health” by regulating drugs, biological products, devices, food, cosmetics, radiation-emitting products, and tobacco products.⁸⁵ Its regulatory authority stems from the federal Food, Drug, and Cosmetic Act (“FDCA”).⁸⁶ Pursuant to the FDCA, FDA utilizes a category-based regulatory structure, whereby the category under which a product falls determines how the agency regulates it.⁸⁷ The regulatory burdens can be extensive or negligible depending on the category, impacting how accessible the product is to the public. I explain below that placenta products could meet the definition of drug, supplement, or human tissue and are therefore subject to FDA regulation under the FDCA.⁸⁸ These three regulatory

Frequently Asked Questions, PLACENTA LADY, <http://www.placentalady.com/faq> (last visited Mar. 25, 2019).

85. *What We Do*, FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Mar. 25, 2019).

86. *Federal Food, Drug, and Cosmetic Act (FD&C Act)*, FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCA/default.htm> (last updated Apr. 21, 2017); *What Does FDA Regulate?*, FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last visited Mar. 25, 2019).

87. *What Does FDA Regulate?*, *supra* note 86.

88. Although the product is primarily sold in intrastate commerce, FDA retains regulatory authority. In *Regenerative Sciences*, the D.C. Circuit found that FDA had the authority to regulate a purely intrastate product to treat orthopedic injuries. *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1317 (D.C. Cir. 2014). The procedure involved providers in Colorado extracting mesenchymal stem cells from a patient's bone marrow, mixing the stem cells with culturing agents and an antibiotic, and then injecting the solution back into the patients. *Id.* at 1318. The mixture FDA sought to regulate in *Regenerative Sciences* is very similar to encapsulated placenta in that both contain a processed form of the individual's extracted tissue or fluid that was transferred back into individual donor. Encapsulated placenta, however, is less processed as it does not contain other ingredients like the mixture in *Regenerative Sciences*. The Court held that because the procedure would “undoubtedly have effects

schemes involve wildly different regulatory burdens for manufacturers. Later in this section, I describe how FDA typically categorizes products that meet multiple categories, but note that FDA has never explicitly categorized a product like encapsulated placenta. Accordingly, it is unclear how the agency might regulate it.

A. The Definitions and Regulatory Requirements for Drugs, Supplements, and Human Tissues

Encapsulated placenta could meet the definition of a drug, supplement, or human tissue. Of these three categories, drugs are regulated the most intensely and supplements, the least intensely. As you will see below, each regulatory category aims to prevent different kinds of harms. Drug regulation fundamentally aims to protect consumers from the risks of unsafe or ineffective novel treatments for disease. The supplement regulations, by contrast, regulate products that are not intended to treat disease, but to supplement the diet; they are therefore aimed at preventing manufacturers from marketing their products with disease claims that the manufacturer did not prove through the rigorous drug approval process. The human tissue regulations are bifurcated. Some human tissue products are regulated as drugs, while other less-risky products are regulated only according to a subset of regulations that are primarily aimed at stopping the spread of communicable disease. The discussion below highlights how encapsulated placenta's categorization will dramatically impact not only the product's availability and price, but also the amount of information we have about its safety and effectiveness.

1. Drugs: Premarket Review for Safety and Effectiveness

FDA defines a drug as a "tablet, capsule, or solution, that contains a drug substance," which is defined as an ingredient intended for use "in the diagnosis, cure, mitigation, treatment, or prevention of disease

on interstate markets for orthopedic care" and one ingredient of the mixture was shipped in interstate commerce, "[t]he Commerce Clause poses no obstacle to regulating the Mixture under the FDCA." *Id.* at 1320. The D.C. Circuit was also unwilling to accept the providers' argument that their product was not regulated by the FDCA because the statute itself only prohibits interstate conduct, like shipping a misbranded or adulterated product through interstate commerce. *Id.* The First and Ninth Circuits have held similarly. *Baker v. United States*, 932 F.2d 813, 814 (9th Cir. 1991); *United States v. Dianovin Pharm., Inc.*, 475 F.2d 100, 102–03 (1st Cir. 1973).

or to affect the structure or any function of the human body.”⁸⁹ Drugs that are created out of human cells and tissues are called biological products or biologics—a subset within the drug category that has its own requirements, but must also undergo premarket review.⁹⁰ Encapsulated placenta could meet this definition. It is a capsule containing an ingredient that certain manufacturers intend to mitigate, treat, and prevent post-partum diseases, like depression, mood disorders, and anemia.

Drugs are held to the highest standard of FDA review. Drugs, including biologics, may not be sold or marketed until they have successfully completed the rigorous FDA premarket approval process.⁹¹ This process requires the drug manufacturers to prove—generally through multiple phases of double-blind, placebo-controlled studies—that their product is both safe *and* effective.⁹² Drug companies must first demonstrate safety and efficacy in animal studies before completing three phases of human trials, each requiring extensive ethics and scientific review.⁹³ It can take over a decade, and cost tens of millions of dollars, to build the evidentiary support to obtain FDA approval.⁹⁴ And of course, it is not always successful; if the results reveal at any point in the process that the drug is not safe or effective, the drug will be denied approval and the manufacturer’s investment will be wasted. Only about one in six drugs that enter the first phase of clinical trials obtain FDA’s approval, underscoring how difficult and expensive FDA regulations

89. 21 C.F.R. § 314.3(b) (2017); *see also* *Drugs@FDA Glossary of Terms*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/informationondrugs/ucm079436.htm> (last visited Mar. 25, 2019).

90. *Drugs@FDA Glossary of Terms*, *supra* note 89.

91. *Development & Approval Process (Drugs)*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/developmentapprovalprocess/default.htm> (last visited Apr. 3, 2019).

92. Greer Donley, *A System of Men and Not of Laws: What Due Process Tells Us About the Deficiencies in Institutional Review Boards*, 7 NW. INTERDISC. L. REV. 197, 215–16 (2014); *Drug Study Designs—Information Sheet*, FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126501.htm> (last visited Mar. 25, 2019); *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last visited Mar. 25, 2019) [hereinafter *The FDA’s Drug Review Process*].

93. Donley, *supra* note 46, at 49–51; *The FDA’s Drug Review Process*, *supra* note 92.

94. Donley, *supra* note 46, at 49–51; Aylin Sertkaya et al., *Key Cost Drivers of Pharmaceutical Clinical Trials in the United States*, 13 CLINICAL TRIALS 117, 117, 120 (2016) (showing that the average cost of a Phase III clinical trial alone was \$11.5 million to \$52.9 million).

make drug development.⁹⁵ This extensive burden, however, is justified by the serious harms posed by unregulated drugs, the public's need for research on the drug's benefits and risks, and the financial advantages these companies enjoy if their product is approved. Unlike supplements, which typically have a history of safe use,⁹⁶ new drugs involve ingredients that have never been consumed by humans and the effects are therefore entirely unknown.

Perhaps the most important advantage FDA grants drug manufacturers is five years of regulatory exclusivity "for new chemical entities not previously approved by the FDA."⁹⁷ Exclusivity gives drug manufacturers a short-term monopoly to incentivize innovation and allow them to recoup the money invested in the drug's development and approval.⁹⁸ Regulatory exclusivity runs concurrently with patent protection, but often lasts longer for drugs whose patents expire while the manufacturer was conducting the research necessary for FDA approval.⁹⁹ In the years of market exclusivity, the manufacturer can make billions of dollars from the benefits of its monopoly, which include the ability to hike up drug prices.¹⁰⁰ And perhaps equally important to manufacturers is the fact that insurance companies pay for prescription FDA-approved drugs, which can also dramatically increase the price manufacturers can charge; by comparison, consumers generally pay for supplements out of pocket, which forces manufacturers to keep prices down or lose customers.

95. Rebecca Dresser, *The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631, 1635 (2015).

96. Supplements must have either been marketed for at least thirty years or be currently in the food supply; if not, they must obtain new dietary ingredient approval. 21 U.S.C. § 350b(d) (2011); 21 U.S.C. § 350b(a)(1) (2011); FOOD & DRUG ADMIN., DIETARY SUPPLEMENTS: NEW DIETARY INGREDIENT NOTIFICATIONS AND RELATED ISSUES: GUIDANCE FOR INDUSTRY 10, 13 (2016), <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM515733.pdf> [hereinafter FDA, DIETARY SUPPLEMENTS].

97. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359–60 (2007) (citing 21 U.S.C. § 355(j)(5)(F)(ii–iii)). FDA also provides three years of market exclusivity for products that make "changes in a previously approved product that required conducting new clinical trials to win FDA approval." *Id.*

98. *Id.* at 361. There is big caveat, however, for products that are widely available before obtaining FDA approval: FDA must choose to enforce the exclusivity. See *infra* notes 117, 267.

99. Eisenberg, *supra* note 97, at 360.

100. Kate Greenwood, *The Mysteries of Pregnancy: The Role of Law in Solving the Problem of Unknown but Knowable Maternal-Fetal Medication Risk*, 79 U. CIN. L. REV. 267, 313–14 (2011) (explaining that just six months of exclusivity can lead to hundreds of millions of dollars); Donley, *supra* note 46, at 85–87.

Another benefit of premarket approval is that manufacturers may market their product as safe and effective at treating, preventing, or mitigating the disease or condition for which it was approved (“disease claims”). Disease claims are special, and only drug manufacturers are allowed to make them—only they have produced the research necessary to prove efficacy.¹⁰¹ Drug manufacturers are nevertheless still prohibited from marketing their drug as effective at treating a condition for which the drug was *not* approved, even though physicians can prescribe drugs for unapproved or “off-label” uses.¹⁰² But as explored below, encapsulated placenta manufacturers do not stand to benefit from exclusivity as typical drug manufacturers; as a result, classification as a drug would come with few benefits and enormous costs.

2. Supplements: Enter the Market Directly

Encapsulated placenta could also fit within the definition of a dietary supplement. FDA defines a dietary supplement as a product intended for ingestion that contains a “dietary ingredient” intended to add further nutritional value to or otherwise supplement the diet.¹⁰³ Dietary ingredients include, for instance, vitamins, minerals, and amino acids.¹⁰⁴ Supplements can be tablets, capsules, powders, energy bars, and liquids.¹⁰⁵ Encapsulated placenta contains numerous vitamins—including iron, manganese, rubidium, selenium, and zinc—and therefore could meet the definition of a supplement.¹⁰⁶

Supplements are regulated very differently from drugs, which require FDA approval before entering the market. Instead, most supplements enter the market directly without any FDA approval.¹⁰⁷

101. See *infra* Section IV.B.1.

102. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES 2 (2011), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf> (noting that it “generally violate[s] the law” when a manufacturer introduces a product into commerce for an intended use that has not been FDA approved, but it is legal for a physician to proscribe the drug for an unapproved use).

103. FDA 101: Dietary Supplements, FOOD & DRUG ADMIN., <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm050803.htm> (last visited Mar. 25, 2019).

104. *Id.* (“Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances,” such as a concentrate, metabolite, constituent, or extract, “that can be used to supplement the diet.”).

105. *Id.*

106. Young, 14 *Trace Minerals*, *supra* note 53, at 876.

107. Dietary Supplements, FOOD & DRUG ADMIN., <https://www.fda.gov/food/dietarysupplements/> (last visited Apr. 3, 2019).

As a result, the manufacturer is not required to conduct any clinical trials demonstrating the product's safety or efficacy. Once on the market, however, FDA has the authority to remove adulterated or misbranded supplements from commerce.¹⁰⁸ But supplements generally enjoy a presumption of safety. This means that unlike drugs, whose manufacturers bear the burden of proving to FDA that their product is safe, FDA cannot pull a supplement from the market until *the agency* proves that the supplement is *unsafe*.¹⁰⁹ The presumption makes it practically difficult for the agency to ban supplements, and many have criticized the supplement regulations for failing to adequately protect consumers.¹¹⁰

One subset of supplements, however, is not presumed safe: supplements containing a “new dietary ingredient” (“NDI”). FDA defines an NDI as “a dietary ingredient that was not marketed in the United States before October 15, 1994,” unless it has “been present in the food supply as an article used for food in a form in which the food has not been chemically altered.”¹¹¹ Encapsulated placenta contains an NDI as human placental tissue is not currently in the food supply and was not marketed in the United States before 1994. Supplement manufacturers hoping to sell a product containing an NDI must also obtain FDA approval before entering the market. At least seventy-five days before the NDI is sold, the manufacturer must submit information to FDA demonstrating that the NDI is “reasonably expected to be safe under the conditions recommended or suggested in the labeling.”¹¹² “[U]nless there is a history of use or other evidence of safety establishing that the new dietary ingredient . . . will reasonably be expected to be safe,” supplements containing NDIs are

108. *Id.*

109. Debra D. Burke & Anderson P. Page, *Regulating the Dietary Supplements Industry: Something Still Needs to Change*, 1 HASTINGS BUS. L.J. 119, 128 (2005); Margaret Gilhooley, *Deregulation and the Administrative Role: Looking at Dietary Supplements*, 62 MONT. L. REV. 85, 119 (2001) [hereinafter Gilhooley, *Deregulation*]; Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed As Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 216 (2009) (“[T]he FDA carries the burden of removing an unsafe or ineffective product by proving that it is adulterated or misbranded.”).

110. See, e.g., Burke & Page, *supra* note 109, at 129–30; Gilhooley, *supra* note 109, at 127; Van Tassel, *supra* note 109, at 251.

111. 21 U.S.C. § 350b(d) (2012); 21 U.S.C. § 350b(a)(1) (2012); FDA, DIETARY SUPPLEMENTS, *supra* note 96, at 10, 13.

112. *New Dietary Ingredients in Dietary Supplements—Background for Industry*, FOOD & DRUG ADMIN., https://www.fda.gov/Food/DietarySupplements/ucm109764.htm#what_is (last updated Aug. 11, 2016) [hereinafter *New Dietary Ingredients*].

considered “adulterated” and selling them is illegal.¹¹³ Recently, FDA announced its intention to revamp its NDI compliance program to ensure that the agency is reviewing the safety of products containing NDIs.¹¹⁴

The NDI approval process is much less rigorous than the premarket approval process for drugs. First, the supplement manufacturer need not prove efficacy, only safety. And second, the manufacturer need not prove safety through double-blind, placebo-controlled studies. Rather, supplement manufacturers can show the NDI’s safety with “safety studies,” “adequate history of safe use,” and even “animal testing.”¹¹⁵ Of course, the safety standard is not perfunctory; FDA only approves roughly 30% of new dietary ingredient applications (though some of the rejected NDIs contain very obvious safety issues).¹¹⁶

In 2002, a company selling encapsulated sheep placenta sought NDI approval from FDA.¹¹⁷ FDA rejected the application, finding that the company failed to support its assertion that sheep placenta “has been in the United States food market for many years” or that it was safe if used as a supplement.¹¹⁸ FDA noted, however, that the company’s submission failed to meet even the most basic aspects of the NDI application, such as the requirement to include copies of the academic articles supporting its position and an explanation of how they are relevant.¹¹⁹ It is therefore not predictive of how FDA would evaluate a serious NDI application for the related, but

113. *New Dietary Ingredients, supra* note 112.

114. *Statement From FDA Commissioner Scott Gottlieb, M.D., on the Agency’s New Efforts To Strengthen Regulation of Dietary Supplements by Modernizing and Reforming FDA’s Oversight*, FOOD & DRUG ADMIN., <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631065.htm> (Feb. 11, 2019).

115. FDA, DIETARY SUPPLEMENTS, *supra* note 96, at 67; Ashish R. Talati, *New Dietary Ingredient Notifications: A Comprehensive Review and Strategies for Avoiding FDA Objections*, 62 FOOD & DRUG L.J. 387, 395 (2007) (“[T]here is no limitation on what evidence a manufacturer/distributor can use for this safety determination. FDA will consider animal and human toxicology data and any citation to published articles or other evidence that is the basis on which the manufacturer or distributor has concluded that the new dietary supplement will provide this reasonable expectation of safety.”).

116. Talati, *supra* note 115, at 390. DMAA was rejected because the ingredient was found to cause shortness of breath, high blood pressure, and heart attack. *DMAA in Products Marketed as Dietary Supplements*, FOOD & DRUG ADMIN. (Aug. 2018), <https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm346576.htm>.

117. FOOD & DRUG ADMIN., FDA-2003-S-0732, NDI 139 - Sheep Placenta from YAT CHAU (USA) INC. (Nov. 22, 2002), available at <https://www.regulations.gov/document?D=FDA-2003-S-0732-0057>

118. *Id.*

119. *Id.*

distinguishable, human placenta. Given the influx of research studying placentophagy in the past five years—including the first clinical trial—and its lack of adverse events for women consuming properly processed placenta,¹²⁰ manufacturers should be able to make a good case that encapsulated placenta is “reasonably expected to be safe” when properly processed and obtain approval as a new dietary ingredient.

While avoiding onerous market-entry requirements, supplement manufacturers do not enjoy the same benefits as drug manufacturers. First, they are not entitled to market exclusivity.¹²¹ This is reasonable because supplement manufacturers do not make the same investment in research as drug manufacturers. As a result, exclusivity as a mechanism to recapture lost investment is unnecessary.

Second, it is illegal for supplement manufacturers “to market a dietary supplement product as a treatment or cure for a specific disease, or to alleviate the symptoms of a disease.”¹²² FDA often issues warning letters to supplement manufacturers that market their products using disease claims.¹²³ Warning letters order a manufacturer to stop making a disease claim or else FDA will remove the product from the market as an unapproved drug.¹²⁴ In 2015, FDA even issued such a warning letter to a company selling encapsulated sheep placenta, claiming that it could improve Alzheimer’s disease, cancer, diabetes, heart disease, multiple sclerosis, and Parkinson’s

120. See *supra* Part I; see *supra* notes 75–77.

121. Supplements already on the market will fail to meet the novelty requirement for patent protection. Eisenberg, *supra* note 97, at 359–60. Though these products could technically obtain FDA exclusivity if they were to be approved as a new drug, they would be dependent on FDA to enforce the exclusivity, which FDA does not always do. For instance, FDA approved as a drug a hormone that was already on the market, yet it declined to enforce the manufacturer’s exclusivity due to concerns with patient access. If FDA were to approve a widely-available supplement as a drug, the agency would be under similar pressure to not enforce exclusivity. Rachel E. Sachs & Carolyn A. Edelstein, *Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation*, 2 J. L. & BIOSCIENCES 396, 404–05 (2015).

122. *FDA 101: Dietary Supplements*, FOOD & DRUG ADMIN., <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm050803.htm> (last updated July 15, 2015).

123. Of the warning letters FDA has issued in 2017, two have been related to supplement manufacturers making illegal health claims (Biomim Industries and Total Body Nutrition). *2017 Warning Letters, Inspections, Compliance, Enforcement, and Criminal Investigations*, FOOD & DRUG ADMIN., <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/default.htm> (last updated Mar. 31, 2019) [hereinafter *2017 Warning Letters*].

124. See, e.g., *Warning Letters*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/complianceenforcement/warning-letters/default.htm>.

disease.¹²⁵ The privilege of making disease claims is reserved for the manufacturers whose products have been proven to be effective at curing, treating, mitigating, or preventing disease, which is not generally true for supplements.

In contrast, FDA regulations allow supplement manufacturers to make structure and function claims about their products: “Dietary supplement labels . . . may . . . bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans . . . provided that such statements are not disease claims”¹²⁶ Manufacturers may also make nutrient deficiency claims.¹²⁷ Before making a structure, function, or nutrient deficiency claim, FDA requires that manufacturers: (1) “have substantiation that the claims are truthful and not misleading,” (2) notify FDA of the claim within thirty days, and (3) “include a mandatory disclaimer.”¹²⁸ The disclaimer must state: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”¹²⁹ FDA imposes a less rigorous standard on structure, function, and nutrient deficiency claims because those claims are less likely to be “beyond the ability of the consumer to evaluate.”¹³⁰ As one might imagine, however, the line between a disease claim and a structure or function claim is not always clear, and courts may be unwilling to enforce FDA determinations that a manufacturer cannot make a particular health claim.¹³¹

Supplement manufacturers must also abide by good manufacturing practice rules, which set standards for the quality of the ingredients, the cleanliness of the facility, and the maintenance of

125. FOOD & DRUG ADMIN., ADVISORY LETTER—LIFE DECODERS, LLC 1 (2016), <https://www.fda.gov/ICECI/EnforcementActions/AdvisoryLetters/ucm478529.htm> [hereinafter FDA, ADVISORY LETTER—LIFE DECODERS, LLC].

126. 21 C.F.R. § 101.93(f) (2008).

127. *Id.* § 101.93(g).

128. *Guidance for Industry: Structure/Function Claims; Small Entity Compliance Guide*, FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm103340.htm> (last updated Nov. 10, 2017) [hereinafter *Guidance for Industry: Structure/Function Claims*].

129. 21 C.F.R. § 101.93(c) (2008).

130. Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 688 (1997) [hereinafter Gilhooley, *Herbal Remedies*]; see also *infra*, Section IV.B.1.

131. Gilhooley, *Deregulation*, *supra* note 109, at 115–16; see also *Pearson v. Shalala*, 164 F.3d 650, 655–56 (1999). FDA, however, has provided regulations for how to identify disease claims at 21 C.F.R. § 101.93(g)(2).

records and customer complaints.¹³² As part of these rules, manufacturers are legally required to “report to FDA any serious adverse events that are reported to them by consumers or health care professionals.”¹³³ FDA also polices manufacturers’ compliance with these regulations and issues warning letters when its inspections reveal violations.¹³⁴

3. Human Tissues: A Bifurcated Approach

A third possible regulatory characterization of encapsulated placenta could be as a human cell, tissue, and cellular- or tissue-based product (“HCT/PS”). FDA defines HCT/PS as “articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.”¹³⁵ Encapsulated placenta meets this definition because it consists of a human tissue that is intended for transfer¹³⁶ into the person who consumes it.¹³⁷

The HCT/P regulations represent a “tiered, risk-based approach,” which attempt to isolate the HCT/P products that are least likely to cause safety issues and regulate them less stringently.¹³⁸ HCT/PS are regulated in one of two ways: either (A) as a biologic, a subset of drugs

132. See generally Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34751 (June 25, 2007) (to be codified at 21 C.F.R. § 111), <https://www.gpo.gov/fdsys/pkg/FR-2007-06-25/html/07-3039.htm>.

133. FDA 101: Dietary Supplements, *supra* note 122.

134. In 2017, three supplement manufacturers (Create-a-Pack Foods, Nexagen, and Total Body Nutrition) received a warning letter for violations of the good manufacturing practice rules. 2017 Warning Letters, *supra* note 123.

135. 21 C.F.R. § 1271.3(d) (2008). The definition also excludes eight categories of products from this definition, none of which are relevant to this Article. *Id.*

136. “Transfer means the placement of human reproductive cells or tissues into a human recipient.” *Id.* § 1271.3(g).

137. Encapsulated placenta could possibly escape HCT/P regulation entirely through an exception for articles “secreted or extracted from human products, such as milk, collagen, and cell factors.” *Id.* § 1271.3(d)(3) (2008). Though the placenta is secreted through the normal birth process, it is unclear whether FDA would find that the product meets this exception. For instance, the agency regulates products made from the amniotic membrane and umbilical cord as HCT/PS even though they too were secreted during birth. FOOD & DRUG ADMIN., REGULATORY CONSIDERATIONS FOR HUMAN CELL, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS: MINIMAL MANIPULATION AND HOMOLOGOUS USE 10, 15 (2017), <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585403.pdf> [hereinafter FDA, REGULATORY CONSIDERATIONS FOR HCT/PS]

138. FDA, REGULATORY CONSIDERATIONS FOR HCT/PS, *supra* note 137, at 2.

made from human, animal, or microorganism sources that are also required to undergo premarket review,¹³⁹ or (B) under less-burdensome regulations found in Section 361 of the Public Health Service Act.¹⁴⁰ If the latter, they are designated “361 HCT/Ps.” HCT/P manufacturers¹⁴¹ qualify for these less onerous regulations if they satisfy the four elements of 21 C.F.R. § 1271.10(a). These elements require that (1) “[t]he HCT/P is minimally manipulated”;¹⁴² (2) “[t]he HCT/P is intended for homologous use only,”¹⁴³ which means that the human tissue must “perform[] the same basic function or functions in the recipient as in the donor”;¹⁴⁴ (3) “[t]he manufacture of the HCT/P does not involve the combination of the cells or tissues with another article”;¹⁴⁵ and (4) either:

- (i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
- (ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
 - (a) Is for autologous use;
 - (b) Is for allogeneic use in a first-degree or second-degree blood relative; or
 - (c) Is for reproductive use.¹⁴⁶

If a product qualifies as a 361 HCT/P by satisfying all four elements, it is not required to undergo premarket review.¹⁴⁷ Instead,

139. *Biological Product Definitions: What Is a Biological Product?*, FOOD & DRUG ADMIN. 1, <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM581282.pdf> (last visited Mar. 25, 2019).

140. 21 C.F.R. §§ 1271.10(a), 1271.20 (2008).

141. FDA defines a HCT/P manufacturer as one who “recover[s], process[es], stor[es], label[s], packag[es], or distribut[es] . . . any human cell or tissue.” 21 C.F.R. § 1271.3(e) (2008). Placenta encapsulators, at a minimum, recover, process, and store human tissue and would therefore be regulated as HCT/P manufacturers. See definitions of process, store, and recover at 21 C.F.R. § 1271(ff), (ii), and (jj).

142. 21 C.F.R. § 1271.10(a)(1) (2008).

143. *Id.* § 1271.10(a)(2).

144. *Id.* § 1271.3(c).

145. *Id.* § 1271.10(a)(3). This excludes “water, crystalloids, or a sterilizing, preserving, or storage agent.” *Id.*

146. *Id.* § 1271.10(a)(4).

147. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: REGULATION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS), SMALL ENTITY COMPLIANCE GUIDE 3 (2007), <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissu>

FDA dictates that 361 HCT/P manufacturers must simply: (1) register with FDA and list the HCT/Ps they manufacture;¹⁴⁸ (2) abide by good manufacturing guidelines that establish minimum sanitary, safety, and competence procedures for sites that handle human tissues;¹⁴⁹ (3) report adverse events; and (4) allow FDA to inspect facilities for compliance.¹⁵⁰ If the placenta were to be consumed by anyone other than the woman from whom it came, the manufacturer would also be required to abide by strict donor eligibility requirements.¹⁵¹ The 361 HCT/P regulations prevent manufacturers from mixing tissues, failing to sanitize the tools and spaces used to process tissues, and creating an environment where human tissues can be cross-contaminated. However, if the four requirements of 21 C.F.R. § 1271.10(a) are not met, then the HCT/P is regulated as a biologic requiring premarket review as described in Section II.A.¹⁵²

Encapsulated placenta easily satisfies elements three and four of 21 C.F.R. § 1271.10(a). Placentophagy providers do not mix the tissue with another article (satisfying element three) and, even though placenta pills have a systemic effect, they are used autologously, meaning that the donor is also the recipient (satisfying element four).¹⁵³ Encapsulated placenta manufacturers, however, will be unable to establish compliance with elements one and two. The first element requires the product to only be minimally manipulated,¹⁵⁴ which is defined as “processing¹⁵⁵ that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement.”¹⁵⁶ The relevant biological

e/ucm062592.pdf [hereinafter FDA, REGULATION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)].

148. 21 C.F.R. §§ 1271.21–.37 (2008).

149. *Id.* § 1271.145–.320.

150. *Id.* § 1271.330–.440.

151. *Id.* § 1271.45–.90.

152. *Id.* § 1271.20.

153. *Id.* § 1271.3(a).

154. *Id.* § 1271.10(a)(1).

155. “Processing . . . includes cutting, grinding, shaping, culturing, enzymatic digestion, and decellularization.” FDA, REGULATORY CONSIDERATIONS FOR HCT/PS, *supra* note 137, at 7.

156. 21 C.F.R. § 1271.3(f)(1) (2008). This is the definition of minimal manipulation for “structural tissues.” *Id.* For “cells and nonstructural tissues,” minimal manipulation is defined as “processing that does not alter the relevant biological characteristics of cells or tissues.” *Id.* § 1271.3(f)(2). FDA has issued guidance on how to distinguish between structural and nonstructural tissues. “Tissues that physically support or serve as a barrier or conduit, or connect, cover, or cushion in the donor are generally considered structural tissues for the purposes of determining the applicable regulatory definition.” FDA, REGULATORY

characteristics for structural tissues “generally include the properties of [the cells or nonstructural tissues] in the donor that contribute to the cells or tissue’s function or functions.”¹⁵⁷ Because the placenta, once encapsulated and consumed by mouth, is not intended to have the same function as it did as an organ inside pregnant women, the placenta is more than minimally manipulated. For instance, FDA has stated that if a manufacturer grinds “amniotic membrane and packages it as particles” then the “HCT/P generally is considered more than minimally manipulated because the processing alters the membrane’s physical integrity, tensile strength, and elasticity that allow it to serve as a membranous barrier.”¹⁵⁸

The second element of § 1271.10(a)—requiring that the tissue be intended for homologous use—would also be difficult to demonstrate for encapsulated placenta.¹⁵⁹ “Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.”¹⁶⁰ FDA is concerned about non-homologous use “because there is less basis on which to predict the product’s behavior, whereas HCT/Ps for homologous use can reasonably be expected to function appropriately.”¹⁶¹ FDA has also made clear that this requirement is necessary even when the donor is the same as the recipient.¹⁶² Homologous use is established, for instance, when a heart valve is used to replace a dysfunctional heart valve or skin replaces damaged skin.¹⁶³ Homologous use therefore requires a very similar showing as minimal manipulation—that the tissue functions the same way inside the recipient as it did inside the donor. Though distinct categories, these elements bleed into one another.

CONSIDERATIONS FOR HCT/PS, *supra* note 137, at 7. FDA’s examples of structural tissue include bone, skin, and amniotic membranes. *Id.* at 8. By contrast, “[c]ells or nonstructural tissues are generally those that serve predominantly metabolic or other biochemical roles in the body such as hematopoietic, immune, and endocrine functions.” *Id.* at 13. Examples of nonstructural tissue include reproductive cells or tissues, cord blood, amniotic fluid, and lymph nodes. *Id.* at 13–14. Although an argument could be made that placenta falls within either category, it most clearly fits as a structural tissue because like the amniotic membrane—the innermost part of the placenta—the placenta acts as a barrier or conduit between the mother and fetus.

157. FDA, REGULATORY CONSIDERATIONS FOR HCT/PS, *supra* note 137, at 6.

158. *Id.* at 10.

159. 21 C.F.R. § 1271.10(a)(2) (2008).

160. *Id.* § 1271.3(c) (2008).

161. FDA, REGULATORY CONSIDERATIONS FOR HCT/PS, *supra* note 137, at 4.

162. *Id.* at 15 (clarifying that the regulation includes “when such cells or tissues are for autologous use”).

163. *Id.*

In short, the transformation of an organ that once served as a conduit between mother and fetus into an oral, powder-based pill would fail to meet both the minimal manipulation and homologous use elements. As a result, if encapsulated placenta were regulated as a human tissue, it would be required to obtain premarket approval as a biologic.

* * *

To summarize, encapsulated placenta arguably meets the definition of a drug, supplement, and human tissue. Its categorization will have enormous effects on how the product is regulated. If FDA decides to treat it as a drug, it would be subject to premarket review and the manufacturers will have to spend tens of millions of dollars over many years collecting the research required to prove that the product is safe and effective before it can be sold. The product will never enter the market if researchers cannot prove its efficacy. Supplements, on the other hand, can generally enter the market directly without FDA approval and remain there unless FDA proves that it is unsafe or that the manufacturer is making disease claims. But because encapsulated placenta contains a new dietary ingredient, manufacturers would be required to demonstrate safety before selling it as a supplement, albeit through a much less rigorous system than that required for drugs. Supplements are not required to be effective at anything to be sold, but manufacturers are limited in the claims they can make. Finally, if encapsulated placenta is a human tissue, it could be regulated as a biologic requiring premarket review or enter the market directly as a 361 HCT/P, required only to abide by regulations aimed at stopping the spread of communicable diseases. Encapsulated placenta, however, would likely fail to meet the 361 HCT/P elements, and therefore be regulated as a biologic.

B. Intended Use: FDA's Method for Categorizing Mixed Products

Encapsulated placenta is certainly not the only product that meets multiple FDA categories, but FDA has never before categorized—or provided guidance on how to categorize—a *human tissue* that meets multiple categories. FDA's general approach to categorizing mixed products¹⁶⁴ is to regulate the product based on its intended use ("Intended Use"). Intended Use refers to "the objective intent of the

164. This is a term I created to describe products that meet multiple categories. To my knowledge, FDA does not utilize a term to describe these products.

persons legally responsible for the labeling of [products]. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article."¹⁶⁵ In other words, when a product could meet multiple definitions, FDA determines under which category the manufacturer intends the product to fall and regulates it accordingly. Intended Use is generally established by reference to "labeling claims, advertising matter, or oral or written statements by such persons or their representatives."¹⁶⁶

Intended Use is most frequently invoked when FDA is confronted with products that could be either supplements or drugs—i.e., products that contain a dietary ingredient but could be used to treat disease. If the manufacturer markets the product as capable of diagnosing, treating, curing, or preventing disease, then the manufacturer intends the product to be a drug and it will be regulated as a drug.¹⁶⁷ However, if the product meets the definition of a supplement and the manufacturer markets it as a supplement—without making disease claims—then FDA will regulate it as a supplement.¹⁶⁸ Unfortunately, many products enter the market as supplements and illegally make disease claims; in those instances, FDA will issue a warning letter to the manufacturer describing the improper statements and directing it to either remove the claims or seek premarket approval to market the product as a drug.¹⁶⁹ FDA can remove a product from the market if it does not comply. Given the enormous burden of drug regulation, manufacturers almost always alter their marketing to remove any disease claims and continue to be regulated as a supplement. As a result, any rational encapsulated placenta manufacturer would avoid making disease claims to prevent drug regulation under the Intended Use paradigm.¹⁷⁰

But assuming that encapsulated placenta manufacturers cease all disease claims, the agency would still have a choice to make: regulate encapsulated placenta purely as a supplement, probably requiring

165. 21 C.F.R. § 801.4 (2008).

166. *Id.*

167. *Guidance for Industry: Structure/Function Claims*, *supra* note 128.

168. *Id.* In certain circumstances, however, FDA will exercise enforcement discretion to allow supplement manufacturers to make disease claims that have been sufficiently proven. *See, e.g., Qualified Health Claims*, FOOD & DRUG ADMIN., <https://www.fda.gov/Food/LabelingNutrition/ucm2006877.htm> (last updated Feb. 2, 2019).

169. *See 2017 Warning Letters*, *supra* note 123.

170. FDA even issued such a warning letter to a manufacturer selling sheep placenta with disease claims. FDA, ADVISORY LETTER—LIFE DECODERS, LLC, *supra* note 125, at 1.

new dietary ingredient approval, or regulate it as a human tissue. Theoretically, Intended Use should involve the same calculus for human-tissue supplements as it does for drug supplements. After all, human tissues are a subset of biologics, which are a subset of drugs.¹⁷¹ But unlike drugs, which are defined by their intent *for use*—to treat disease¹⁷²—human tissues are defined by their intended *destination*—“human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.”¹⁷³ Thus, avoiding human tissue regulation may not be as easy as avoiding drug regulation. If the product is a human tissue intended for transfer into a recipient, there is no easy marketing fix to stave off the human tissue regulations, even assuming the tissue is solely intended to supplement the diet.

FDA has never directly answered how it would regulate products that are both human tissues and supplements. Probiotics present the most similar case study. As live micro-organisms, probiotics are both biologics and supplements.¹⁷⁴ FDA’s current approach has been to regulate probiotics on a case-by-case basis, sometimes as supplements, sometimes as food, sometimes as drugs.¹⁷⁵ FDA seems primarily concerned about whether probiotics found within supplements or conventional foods are marketed with drug claims, not whether the live microorganisms are properly handled under the biologic regulations.¹⁷⁶ And thus far, meeting the definition of a biologic has not usurped a probiotic’s ability to be regulated as a supplement. The University of Maryland recently published a ninety-

171. *Frequently Asked Questions About Therapeutic Biological Products*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/ucm113522.htm> (last updated July 7, 2015).

172. FDA defines a drug as “contain[ing] a drug substance,” which is an ingredient intended for use “in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body.” 21 C.F.R. § 314.3(b) (2008).

173. 21 C.F.R. § 1271.3(d) (2008). The definition also excludes eight categories of products from this definition, none of which are relevant to this Article. *Id.*

174. DIANE E. HOFFMANN ET AL., FINAL REPORT: FEDERAL REGULATION OF PROBIOTICS: AN ANALYSIS OF THE EXISTING REGULATORY FRAMEWORK AND RECOMMENDATIONS FOR ALTERNATIVE FRAMEWORKS 19–20 (2016), <https://www.law.umaryland.edu/media/SOL/pdfs/Programs/Health-Law/FinalWhitePaper.pdf> (“FDA considers probiotics to be biological products”).

175. *Id.* at 19.

176. See, e.g., *Warning Letter for Bio TE Medical*, FOOD & DRUG ADMIN. (May 22, 2017), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm561444.htm>.

page report with recommendations on how to regulate probiotics,¹⁷⁷ but FDA has yet to establish a long-term position.¹⁷⁸

If FDA decided to regulate encapsulated placenta as a human tissue because it is intended for transfer into a human recipient, then encapsulated placenta manufacturers would be forced to obtain premarket review. As a reminder, the HCT/P regulations are bifurcated. Products either meet the elements of a 361 HCT/P, which are regulated lightly, or must obtain premarket approval as a biologic. As noted in Section II.A.3, encapsulated placenta fails to meet two of the four criteria for 361 HCT/P regulation: minimal manipulation and homologous use.¹⁷⁹ It would therefore be regulated under FDA's strictest standard. Alternatively, if FDA chooses to ignore the human tissue regulations—as it has (at least temporarily) ignored the biologic regulations for probiotics—then encapsulated placenta would be regulated as either a drug or supplement depending on whether it made disease claims. Practically speaking, under this scenario, encapsulated placenta manufacturers would drop disease claims and be regulated as supplements.

FDA's regulatory scheme does not provide clear answers on how encapsulated placenta should be regulated. In light of this uncertainty, a policy analysis would be particularly useful at illuminating the ideal categorization available to the agency. Part III explores two policy considerations that the agency should consider in regulating encapsulated placenta: the need to balance consumer safety against consumer access and the gender-based implications surrounding the state's regulation of products associated with fertility and childbirth. These considerations suggest that though some regulation of encapsulated placenta is needed to establish a safety floor, it should not be so stringent that women lose access to the product.

177. See generally HOFFMANN ET AL., *supra* note 174.

178. There is reason to think FDA might not be so lenient for encapsulated placenta. Probiotics have been consumed safely in conventional foods like yogurt for many years, which might cause the agency to feel more comfortable leaving them less regulated.

179. See *supra* Section II.A.3.

III. PUBLIC POLICY CONCERNS IN REGULATING PLACENTOPHAGY

In evaluating whether and how to regulate a product, FDA must balance competing goals. Its primary purpose is to protect the public from the risks of unsafe or ineffective products.¹⁸⁰ But FDA is also mandated to help ensure that health-related innovations are accessible to the public.¹⁸¹ These two values are often in tension as FDA balances the public's interest in having immediate access to a new treatment against its need to be protected from unknown harms.¹⁸² For any given product, the balance of these two interests yields different results on how much regulation is required.

Fundamentally, FDA's category-based regulatory system reflects the notion that different kinds of products, with their varying levels of risk, should be regulated differently. Drugs are regulated the most extensively because they pose the greatest risk of harm, while conventional foods are regulated very lightly because it is generally considered safe.¹⁸³ Concerns over consumer access are also encompassed in each category's regulatory structure. Because the patent system financially incentivizes the creation of novel drugs, burdensome regulations for drugs are less likely to diminish a consumer's long-term access to medications, whereas products for which market exclusivity is unavailable—like supplements and conventional foods—must be regulated less harshly to ensure that the product does not disappear from the market entirely.¹⁸⁴ Thus, at least at a high level, the regulations governing each of FDA's categories can be construed as striking a particular balance between consumer access and consumer safety as related to that class of products. These concepts are explored in greater detail throughout this Article.

Mixed products are more complicated, however, because they do not easily fit into any of FDA's predetermined categories. FDA is therefore faced with a dilemma: Should it regulate the product according to the more rigorous or more lenient system? Should it regulate the product according to one category or multiple categories? Or if the product is unique, should it craft freestanding regulations to govern it or leave it completely unregulated? It is exactly in these ambiguous circumstances that the policy concerns underlying FDA regulation can best guide agency decision-making.

180. *What We Do*, *supra* note 85.

181. *Id.* ("FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable.").

182. *See infra* Part III.

183. *See infra* Part III; *see also* HOFFMANN ET AL., *supra* note 174, at 21.

184. *See infra* Section II.A.

This Part starts with an examination of the policy values that must be balanced for all FDA regulation: consumer access and consumer safety. I look to how these goals are balanced for supplements and drugs as a way to explain placentophagy advocates' countervailing concern about the regulation of encapsulated placenta. It then explores of the centrality of gender to any debate of whether to regulate a product associated with childbirth and fertility, especially in light of the criticism that the state tends to overregulate women's bodies immediately before, during, and after pregnancy. Both of these discussions reveal the need to regulate the product on some level, but not so much as to render it unavailable.

A. *Balancing Consumer Safety Against Consumer Access*

The tension between consumer access and safety is ever present in the debate over FDA regulation, whether the dispute is about a specific product or a class of products.¹⁸⁵ Regarding safety, FDA regulation protects consumers against misinformation and adulteration by ensuring that manufacturers are not fabricating miracle cures, releasing dangerous and untested products onto the market, or lying about their products' benefits.¹⁸⁶ Just this year, the World Health Organization found that over 10% of the drugs sold in the developing world—where the pharmaceutical industry is less regulated—are substandard or falsified, which has led not only to consumers unknowingly spending their money on knock-offs, but the progression of serious illness and death to patients consuming them.¹⁸⁷ FDA's regulatory protection, however, comes with a negative

185. Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 AM. J.L. & MED. 687, 691 (2016) (describing the "sometimes contrary" fundamental purposes of FDA: (1) "guarding the public health by protecting consumer from hazardous and ineffective products" and (2) "promoting the expeditious release of potential effective treatments, both to advance public health and to enhance consumer choice"); Eisenberg, *supra* note 97, at 346 ("Throughout this period the most politically compelling arguments in favor of regulation emphasized public health and the protection of patients from unknown hazards, while the most compelling arguments against regulation emphasized the interests of patients and doctors in making their own therapeutic choices unfettered by government regulation."); Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 LEGIS. & PUB. POL'Y 295, 296 (2000) (describing the costs and benefits of FDA regulation).

186. See generally *Developments in the Law—the Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632 (1954).

187. *1 in 10 medical products in developing countries is substandard or falsified*, WORLD HEALTH ORG. (Nov. 28, 2017), <http://www.who.int/mediacentre/news/releases/2017/substandard-falsified-products/en/>.

side effect: reduced access to helpful medications. FDA regulation can prevent products from entering the market, discourage innovation, raise prices, and waste resources.¹⁸⁸ Reduced access also harms consumers, who miss the benefits of new products, some of which might also be lifesaving while the agency determines if the product is safe and effective.¹⁸⁹

The debate over whether, and how, to regulate encapsulated placenta involves the same tension. Encapsulated placenta providers argue that they cannot afford to abide by burdensome regulations, and thus, if FDA regulates them too harshly, the product will disappear from the market. Others argue, however, that the product is unproven and potentially dangerous. If the government does not regulate it, they say, consumers will be exposed to safety risks and there will be no incentive for anyone to generate data on whether the product actually works.

These same concerns were raised during the national conversation over how to regulate dietary supplements.¹⁹⁰ Before the Dietary Supplement Health and Education Act (“DSHEA”) was passed in 1994, FDA threatened to start enforcing its drug regulations against supplement manufacturers,¹⁹¹ which would have required supplements to obtain premarket approval.¹⁹² Congress passed the DSHEA in response to public outrage that individuals might lose access to supplements if manufacturers were forced to adhere to the harsh premarket approval requirements.¹⁹³ The DSHEA defined

188. Grossman, *supra* note 185, at 691 (“As a formal matter, the Act curbs the conduct of manufacturers and distributors, not their customers. Nevertheless, when the FDA prevents the sale of a product altogether, the Agency also indirectly limits the rights of consumers who want that product.”); Eisenberg, *supra* note 97, at 367 (“[T]he FDA is often criticized as a paternalistic bureaucracy interposing costly barriers between patients who demand new products and firms that are eager to supply them.”).

189. For instance, patient advocates sued FDA arguing that terminally-ill patients have a constitutional right to access investigational drugs. Dresser, *supra* note 95, at 1635–38.

190. Gilhooley, *Deregulation*, *supra* note 109, at 91–93.

191. FDA threatened to start regulating supplements as drugs after thirty-eight people died from consuming an amino acid supplement. *Id.* at 92. Before this, FDA was regulating supplements as food additives. Jennifer Akre Hill, *Creating Balance: Problems Within DSHEA and Suggestions for Reform*, 2 J. FOOD L. & POL’Y 361, 366 (2006). For a comprehensive discussion of the long history of supplement regulation, see Gilhooley, *Herbal Remedies*, *supra* note 130, at 671–79.

192. Hill, *supra* note 191, at 367; see also *infra* Part IV.

193. Ryan Abbott, *Treating the Health Care Crisis: Complementary and Alternative Medicine for PPACA*, 14 DEPAUL J. HEALTH CARE L. 35, 68–73 (2011) (“In 1994, after an attempt by the FDA to restrict commercial availability of dietary supplements, approximately two million letters were sent to members of Congress to

supplements as foods, permitting them to enter the market without FDA approval; but it limited supplement manufacturers' ability to make certain health claims about their products, explored in greater detail below.¹⁹⁴ For instance, supplements cannot be marketed as being able to cure, mitigate, prevent, or treat any disease.¹⁹⁵ Had Congress not enacted the DSHEA, the public's access to supplements would be greatly reduced today.¹⁹⁶

Rebecca S. Eisenberg uses market exclusivity to explain why regulating supplements as drugs would have substantially reduced the public's access to supplements.¹⁹⁷ Premarket approval requires manufacturers to fund expensive research proving that their product is both safe and effective.¹⁹⁸ Unlike supplements, drugs generally enjoy a period of patent exclusivity when they first enter the market.¹⁹⁹ This market exclusivity allows pharmaceutical companies to recoup the money spent on research and utilize the research's findings to market their product without competitors piggybacking off of their work.²⁰⁰ Without exclusivity, however, "competitors can share in the benefits of [the research a manufacturer funds] without sharing in the costs of producing it."²⁰¹ In this situation, there is no incentive to produce the research because the costs cannot be recouped.

Supplement manufacturers are generally excluded from the patent system because patents are only available for discoveries or

fight for consumer access. In justifying the resulting Dietary Supplement and Health Education Act, Congress cited 'overwhelming public pressure' favoring improved access."); Hill, *supra* note 191, at 370-71; Burke & Page, *supra* note 109, at 128. This public concern was due to, at least in part, a supplement industry campaign to persuade the public that the DSHEA would be bad for consumers. Gilhooley, *Deregulation*, *supra* note 109, at 93.

194. Gilhooley, *Herbal Remedies*, *supra* note 130, at 684-86.

195. *FDA 101: Dietary Supplements*, *supra* note 122.

196. Eisenberg, *supra* note 97, at 379-80; Gilhooley, *Deregulation*, *supra* note 109, at 92-93.

197. Eisenberg, *supra* note 97, at 379-80; *see also* Gilhooley, *Herbal Remedies*, *supra* note 130, at 711.

198. Hill, *supra* note 191, at 367.

199. Eisenberg, *supra* note 97, at 379-80.

200. *Id.* at 355.

201. *Id.* at 379; *see also id.* ("Suppose the manufacturer of an unpatented vitamin or dietary supplement believes that it could increase demand for its product by conducting clinical trials to convince skeptics that it is safe and effective. At best, the seller would have to share the expanded market with competitors who did not share in the cost of information provision."); Gilhooley, *Herbal Remedies*, *supra* note 129, at 711 ("The 'gold standard' of controlled scientific testing can be seen as too demanding for natural products when they cannot obtain protection for research that the patent system makes possible for drugs synthesized and developed by pharmaceutical companies.").

creations of novel compounds, and supplements are generally made from naturally occurring ingredients already on the market.²⁰² And though regulatory exclusivity is theoretically available to them, FDA has an uneven history in enforcing the exclusivity when a product had previously been sold by multiple providers.²⁰³ The fact that supplement manufacturers cannot “capture the value of clinical trials” through market exclusivity indicates that “[i]f dietary supplements were subjected to the same regulatory standards as patented drugs, the most likely result would not be improved information provision, but the disappearance of these products from the market.”²⁰⁴

Proponents of the DSHEA argued that limiting access to supplements would be particularly anomalous given that supplements are generally much less dangerous than drugs.²⁰⁵ There is truth to this; for instance, consumers self-reported 649 deaths caused by pharmaceuticals in 2015.²⁰⁶ By contrast, consumers only

202. Abbott, *supra* note 193, at 68–73; Joshua H. Biesler, *Dietary Supplements and Their Discontents: FDA Regulation and the Dietary Supplement Health and Education Act of 1994*, 31 RUTGERS L.J. 511, 516 n.22 (2000) (“[U]nlike new pharmaceuticals, dietary supplements cannot be patented, and this fact makes the return on this massive investment far from assured in the context of the dietary supplement industry.”); Judd Cooper Legum, *The Dangers of DSHEA: A Case for Expanded FDA Authority over Dietary Supplements*, 6 J. MED. & L. 103, 119 (2002).

203. Rachel E. Sachs & Carolyn A. Edelstein, *Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation*, 2 J. L. & BIOSCIENCES 396, 404–05 (2015); *see supra* note 121.

204. Eisenberg, *supra* note 97, at 379–80; *see also* Legum, *supra* note 202, at 119 (“The rationale behind DSHEA is that if dietary supplements were subject to the same safety standards as drugs, then they would not be available.”).

205. Biesler, *supra* note 202, at 524 (noting “the extremely low number of injuries reported that were attributed to the use of dietary supplements,” especially “[w]hen compared to the injuries and fatalities that result from the use of FDA-approved drugs”).

206. James B. Mowry et al., *2015 Annual Report of the American Association of Poison Control Centers’ National Poison Data System (NPDS): 33rd Annual Report*, 54 CLINICAL TOXICOLOGY 924, 1086 (2016), https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2015_AAPCC_NPDS_Annual_Report_33rd_PDF.pdf. These numbers are typically viewed as under representations; in hospital patients alone, it is estimated that adverse drug reactions cause 106,000 to 128,000 deaths annually, even despite how closely they are regulated. Donald W. Light, *New Prescription Drugs: A Major Health Risk With Few Offsetting Advantages*, HARV. UNIV. (June 27, 2014), <https://ethics.harvard.edu/blog/new-prescription-drugs-major-health-risk-few-offsetting-advantages>; Michael O. Schroeder, *Death By Prescription*, U.S. NEWS (Sept. 27, 2017), <https://health.usnews.com/health-news/patient-advice/articles/2016-09-27/the-danger-in-taking-prescribed-medications>; *Preventable Adverse Drug Reactions: A Focus on Drug Interactions*, FOOD & DRUG ADMIN., www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm110632.htm (last visited Mar. 25, 2019).

reported three deaths caused by vitamins and supplements in the same year.²⁰⁷ This large difference is startling when one considers that FDA extensively regulates pharmaceuticals before they enter the market—and yet the death rate is still comparatively high—and FDA only minimally regulates supplements, and the supplement death rate is nevertheless very low. This is not to say that supplements are categorically safe. Individual supplements can be dangerous,²⁰⁸ and even safe supplements can expose consumers to health risks at certain doses or in particular circumstances.²⁰⁹ But supplements raise significantly fewer safety concerns than pharmaceuticals. Supplements, almost by definition, are products that have been either on the market for decades or are regularly consumed by the public through a normal diet.²¹⁰

For Congress, the need to protect the public's access to supplements outweighed the risk to public safety that supplements posed: the "DSHEA . . . is firmly grounded in Congress' recognition that consumers want information about and access to a broad range of safe products."²¹¹ Congress' determination that supplements did not pose a great enough safety risk to so starkly limit consumer choice was reflected in much of the legislative history associated with the Act.²¹² Proponents believed in a freedom-of-choice theory, which

207. Mowry et al., *supra* note 206, at 1068, 1080–81.

208. For instance, supplements containing ephedrine caused 800 adverse events. Gilhooley, *Deregulation*, *supra* note 109, at 120. FDA also banned L-tryptophan after one manufacturer's product contained a contaminant that caused eosinophilia-myalgia syndrome in 1,500 individuals. Beisler, *supra* note 202, at 528.

209. For instance, supplements can cause adverse health risks when consumed with prescription drugs. See Stephanie Kauflin, *Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme*, 33 SETON HALL L. REV. 411, 411 (2003); Gilhooley, *Deregulation*, *supra* note 109, at 118. And furthermore, consumers may undercount supplement risks because of a psychological phenomenon whereby individuals assume that familiar and natural products are safe. Dana Ziker, *What Lies Beneath: An Examination of the Underpinnings of Dietary Supplement Safety Regulation*, 31 AM. J.L. & MED. 269, 276 (2005).

210. If a supplement contains a dietary ingredient that has not "been present in the food supply as an article used for food in a form in which the food has not been chemically altered," then it is a "new dietary ingredient" and must undergo its own form of premarket review. 21 U.S.C. § 350b(a)(1) (2008); FDA, DIETARY SUPPLEMENTS, *supra* note 96, at 10.

211. Scott Bass & Emily Marden, *The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent*, 31 AM. J.L. & MED. 285, 287 (2005).

212. Senator Orrin Hatch, for instance, stated that "most of these [products] have been on the market for 4,000 years, and . . . there is not much risk." *Legis. Issues Related to the Regulation of Dietary Supplements: Hearing of the Comm. on Labor and Human Res.*, 103d Cong. 60 (1993) (statement of Sen. Orrin Hatch), https://archive.org/stream/legislativeissue00unit/legislativeissue00unit_djvu.txt.

prioritizes access when safety concerns are low.²¹³ And although ample criticism persists about the DSHEA—in particular, whether it sufficiently protects consumers²¹⁴—most critics do not argue that supplements should be held to the same standards as drugs.

Answering the questions of whether and how to regulate placentophagy requires us to resolve the same tension. Placentophagy providers are almost exclusively small business owners selling an unpatentable product.²¹⁵ If FDA were to regulate placenta pills as a drug and require premarket review, the product would most likely disappear from the market—the small placentophagy shops would not have the resources or incentives to fund the research necessary for premarket review.²¹⁶ But the product is largely safe when properly processed, so effectively banning the product seems like an overreaction, even if the product's only benefit is placebo, albeit a

Senator Bill Richardson made expressed a similar view: “this issue is all about—freedom of choice. The safe use of dietary supplements could save this country billions of dollars in health care costs each year if adequate information could be given to the public on labels and pamphlets and the public was allowed to make choices.” *Id.* at 2 (statement of Hon. Bill Richardson).

213. See *supra* note 212; Gilhooley, *Herbal Remedies*, *supra* note 130, at 715 (“If there is a justification for an alternative system with a lower standard of efficacy, it would seem to be to allow the consumer the freedom to use a product even when the efficacy of the product has not been adequately proven so long as use is on an informed basis, the product is safe, and there are safeguards against indirect harm.”). Opponents, however, abide by the “precautionary principle,” whereby new products should not be introduced when the effects are disputed or unknown.

214. Burke & Page, *supra* note 109, at 121 (“Since the FDA can attempt to regulate dietary supplements only after they enter the market, consumers can be at risk, sometimes great risk, of injury from using unsafe products.”); Gilhooley, *Deregulation*, *supra* note 109, at 119 (“A major weakness in DSHEA is that it does not impose on all dietary supplements the burden and obligation to affirmatively substantiate their safety.”).

215. As of March 2019, almost all of the 751 placentophagy providers listed on the Placenta Encapsulation website are individual or small groups. *Find a Placenta Specialist*, FIND PLACENTA ENCAPSULATION, <http://findplacentaencapsulation.com/find-a-placenta-specialist/> (last visited Mar. 25, 2019).

216. Eisenberg, *supra* note 97, at 379–80 (“If dietary supplements were subjected to the same regulatory standards as patented drugs, the most likely result would not be improved information provision, but the disappearance of these products from the market.”). Encapsulated placenta leads to the same results Eisenberg discusses for supplements because it cannot be patented. But even if a placentophagy provider could afford the research, the manufacturer is in a Catch 22: either the research would show that the perceived benefits of encapsulated placenta are almost entirely attributed to the placebo effect, in which case FDA would not approve the product, or the manufacturer would demonstrate efficacy, in which case every placentophagy provider would be able to competitively use the research to market their products even though they did not share in the cost of producing it.

powerful one.²¹⁷ Proponents would mobilize, which is exactly what occurred when Europe attempted to classify placenta as a novel food that could not be sold until after extensive research was completed.²¹⁸ There was a public uproar about the impossibility of funding the research and the impact on accessibility.²¹⁹ Europe has still not finalized the regulation, so it is not yet in force.²²⁰

There is another reason to be particularly worried about overregulation of encapsulated placenta: the potential for a robust do-it-yourself (“DIY”) alternative. Already some women chose to eat their placentas raw or encapsulate it themselves—if the product disappears from the market, even more women will rely on DIY alternatives, which are much less safe.²²¹ Because self-production is not commerce, FDA lacks the jurisdiction to regulate it.²²² Though rare, encapsulated placenta is not the only recent technology to raise this issue.²²³ As discussed in Section IV.B below, FDA has recently started regulating processed, donated stool for fecal transplants—a procedure where donor feces is implanted into a recipient’s colon to treat *C. difficile* infections.²²⁴ Though similarly unconventional, this new treatment has helped many people.²²⁵ Both products are made exclusively from human waste—a resource that is easily accessible for those who want

217. Selander et al., *supra* note 8, at 105. Placebo is powerful, and the benefits it produces should not be easily dismissed. *The Power of the Placebo Effect*, *supra* note 60.

218. Farr et al., *supra* note 2, at 407.

219. See, e.g., *id.*; *My Placenta My Choice*, PLACENTA NETWORK, <https://www.placentanetwork.com/my-placenta-my-choice/> (last visited Mar. 25, 2019); *Placenta Service in Europe Should NOT Be Stopped by Novel Food Regulation (EC) 258/97*, CHANGE.ORG, <https://www.change.org/p/food-standards-agency-placenta-services-in-europe-should-not-be-stopped-by-novel-food-regulation-ec-258-97> (last visited Mar. 25, 2019).

220. Farr et al., *supra* note 2, at 407.

221. Coyle et al., *supra* note 2, at 674; Joseph et al., *supra* note 2, at 478; McCarthy, *supra* note 11.

222. See *supra* note 88.

223. In addition to fecal transplants, another example where the possibility of DIY alternative influenced the extent of government regulation is sperm donation. See Margaret Brazier, *Regulating the Reproduction Business?*, 7 MED. L.R. 166, 170, 179 (1999).

224. FOOD & DRUG ADMIN., ENFORCEMENT POLICY REGARDING INVESTIGATIONAL NEW DRUG REQUIREMENTS FOR USE OF FECAL MICROBIOTA FOR TRANSPLANTATION TO TREAT *CLOSTRIDIUM DIFFICILE* INFECTION NOT RESPONSIVE TO STANDARD THERAPIES 1 (2016), <https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/vaccines/ucm488223.pdf> [hereinafter FDA, ENFORCEMENT POLICY].

225. Sachs & Edelstein, *supra* note 203, at 401.

to make the product themselves.²²⁶ After initially regulating the product through premarket review, FDA ultimately backed off.²²⁷ One concern was that if FDA overregulated the product, it might be exposing consumers to greater risks associated with DIY, amateur production than the consumers would have been exposed to if the product were regulated less stringently and available for purchase from manufacturers.²²⁸ The same concerns exist for encapsulated placenta. FDA should be very resistant to regulations that could make a product that is relatively safe when processed properly, dangerous when consumed raw or after amateur production.

On the other hand, there is little consistency among placentophagy providers, and the product has been on the market long enough to know that there are risks associated with improper handling. Unlike supplements, placentophagy providers are working with a human tissue, which raises real concerns about the spread of communicable diseases. There are no guidelines to ensure that their processing sites are clean, that they do not cross-contaminate placentas, and that they process placentas in such a way that harmful bacteria are killed.²²⁹ Providers can make claims that are misleading or suggest that placenta pills treat post-partum depression—a disease that can be life-threatening if not properly treated.²³⁰ Some FDA regulation is required to protect women from these risks

B. Concerns About the Paternalistic Over-Protection of Women

Gender is central to the debate of whether to regulate encapsulated placenta.²³¹ Women are almost exclusively the product's consumers and manufacturers, and their reproductive decisions are frequently in the spotlight. Though the government regulates healthcare in innumerable ways that affect both genders, laws surrounding pregnancy are politicized and frequently deprioritize a

226. *Id.* at 406.

227. FDA, ENFORCEMENT POLICY, *supra* note 224, at 4.

228. Sachs & Edelstein, *supra* note 203, at 406.

229. See Part I (discussing the risks of placentophagy).

230. See, e.g., Friess, *supra* note 78 (describing an FDA official's comment that a placentophagy provider's website was making unsubstantiated health claims).

231. See Charlotte Kroløkke, Elizabeth Dickinson & Karen A. Foss, *The Placenta Economy: From Trashed to Treasured Bio-Products*, 25 EUR. J. WOMEN'S STUD. 138, 141 (2018) ("Clearly, the placenta economy is gendered. Not only do placentas come from birthing maternal bodies, particular notions of femininity and understandings of women's bodies are inscribed in the ways in which placentas move from women giving birth to female consumers.").

woman's autonomy for the sake of a religious- or value-based goal.²³² As a result, many women are understandably sensitive to the state's intrusion into medical decisions that only women encounter. Laws that purport to promote a woman's safety or informed consent are often pretext for legislation intended to limit access to reproductive health services, such as abortion,²³³ contraception,²³⁴ natural labor,²³⁵ and even participation in medical research while pregnant.²³⁶

Abortion is the obvious example where women's reproductive choices are limited by the government. But over the past five decades, the state has inserted itself increasingly into women's decisions over childbirth:

There are significant regulatory limits on reproductive choices during pregnancy. Regulations surrounding the use of midwives are increasingly restrictive. Moreover, women who want to undergo natural childbirth are increasingly restricted from doing so because of hospital regulations prohibiting natural birth after C-sections, breach births, and other high-risk vaginal deliveries. Home births are increasingly rare as doctors and midwives cannot obtain insurance coverage for attending such births and because of explicit restrictions. The mandatory use of fetal monitoring devices in hospitals is at an all-time high, even when not medically indicated. Thus,

232. Donley, *supra* note 46, at 61, 75 (discussing how FDA's regulation of pregnant women in research and over-the-counter Plan B purports to protect women, but is really a political decision); Pamela Laufer-Ukeles, *Reproductive Choices and Informed Consent: Fetal Interests, Women's Identity, and Relational Autonomy*, 37 AM. J.L. & MED. 567, 582 (2011) ("The focus on women and their needs [in the context of abortion] has been surrendered in pursuit of political aims."); Sylvia A. Law, *Childbirth: An Opportunity for Choice That Should Be Supported*, 32 N.Y.U. REV. L. & SOC. CHANGE 345, 363 (2008) ("Traditions of paternalism and disrespect for patient choice are particularly strong in relation to childbirth and reproduction.").

233. Laufer-Ukeles, *supra* note 230, at 592–93 (describing "informed consent" legislation as "unabashedly biased and reflect[ing] ideological interests of the state as long as it is deemed not misleading or untruthful"); Olga Khazan, *Planning the End of Abortion*, ATLANTIC (July 16, 2015), <https://www.theatlantic.com/politics/archive/2015/07/what-pro-life-activists-really-want/398297/> (describing how Americans United for Life proposes draft legislation for state legislatures to introduce, some of which are purported to protect women's safety and consent).

234. Donley, *supra* note 46, at 61.

235. See, e.g., Laufer-Ukeles, *supra* note 230, at 587 (describing the "regulatory limits on reproductive choices during pregnancy" including restrictions on natural childbirth and the rise of the use of the C-section).

236. Donley, *supra* note 46, at 61.

women's options for non-interventionist births are increasingly limited.²³⁷

Institutional or state rules now govern most aspects of the childbirth process.²³⁸ To the extent that a woman's plans for her child's birth depart from the conventional or institutional expectation, she may feel varying degrees of pressure to conform.²³⁹

These rules are typically justified as necessary to protect women, and it is true that maternal mortality dramatically declined during the time period that women started giving birth in hospitals.²⁴⁰ But they can also work to women's detriment. For instance, the United States has experienced a dramatic increase in the number of births resulting in cesarean section, which are often not in the best interest of the mother.²⁴¹ One-third of U.S. births are through cesarean section, even though the World Health Organization contends that caesarean rates higher than 10% do not reduce maternal or infant mortality.²⁴² And caesarian deliveries greatly increase complications and negatively impact maternal recovery.²⁴³ By comparison, the

237. Laufer-Ukeles, *supra* note 232, at 587.

238. *See id.*; Dara E. Purvis, *The Rules of Maternity*, 84 TENN. L. REV. 367, 396 (2017) ("Many commentators have described birth as increasingly medicalized in recent years and correspondingly increasingly controlled by doctors rather than the laboring mother.").

239. *See, e.g.*, Laufer-Ukeles, *supra* note 232, at 588 (describing the growing "pressure toward intervention" in childbirth, which has limited free choice); Purvis, *supra* note 238, at 397 ("Not only are women pressured and sometimes coerced by their doctors to deliver by c-section, particularly if past deliveries were also by c-section, but the state has repeatedly either punished women for refusing to have a c-section if the baby is arguably harmed by that decision, or actually ordered women to undergo the procedure.").

240. Neal Devitt, *The Transition from Home to Hospital Birth in the United States, 1930-1960*, 4 BIRTH & FAM J. 47, 47 (1977).

241. *See e.g.*, Laufer-Ukeles, *supra* note 232, at 587-88; Purvis, *supra* note 238, at 397; Farah Diaz-Tello, *When the Invisible Hand Wields a Scalpel: Maternity Care in the Market Economy*, 18 CUNY L. REV. 197, 203 (2015) ("The health risks of cesarean surgery are mostly borne by the birthing person, and largely deferred into subsequent pregnancies . . .").

242. Diaz-Tello, *supra* note 241, at 203.

243. AM. COLL. OBSTETRICIANS & GYNECOLOGISTS & SOC'Y FOR MATERNAL-FETAL MED., OBSTETRIC CARE CONSENSUS: SAFE PREVENTION OF THE PRIMARY CESAREAN DELIVERY 1-3 (2014), <https://www.acog.org/-/media/Obstetric-Care-Consensus-Series/oc001.pdf?dmc=1&ts=20171023T1940344583> (noting that "for most pregnancies, which are low-risk, cesarean delivery appears to pose greater risk of maternal morbidity and mortality than vaginal delivery" and that "the downstream [caesarian risks] are even greater because of the risks from repeat cesareans in future pregnancies"); Nancy Ehrenreich, *The Colonization of the Womb*, 43 DUKE L.J. 492, 537 (1993) ("Protecting a fetus often entails imposing certain risks on the woman

Nordic countries perform roughly half as many caesarian sections as the United States,²⁴⁴ but their infant mortality rates are also roughly half of the rates in the United States.²⁴⁵ Furthermore, four to five times more women die in the United States from childbirth-related complications than in Finland, Sweden, and Iceland.²⁴⁶ In other words, American women are subject to the complications, side-effects, and risks of cesarean section twice as often, but they and their children still have much worse outcomes.

Some women in the United States who seek to deliver vaginally are shamed, threatened, or even coerced by courts and hospitals into undergoing a caesarian section against their will or preference.²⁴⁷ This is despite the fact that reasonable people can disagree about whether a caesarian section is truly medically necessary.²⁴⁸ Poor women of color are the most affected by such terrible treatment and also the most likely to die in childbirth.²⁴⁹ Regardless of one's views on the movement towards natural childbirth, it is not clear that the state is always acting in the woman's best interest in recommending (or coercing) an interventionist birth.

The regulation of midwifery presents another apt example of childbirth regulation that may actually harm women, despite being

carrying it; a Cesarean section, for example, is at least twice as likely as a vaginal birth to result in the death of the mother. Yet this risk becomes irrelevant if the cultural norm already prescribes that she be willing to sacrifice anything and everything for her children (born or unborn).”).

244. See *Caesarean Sections*, in HEALTH AT A GLANCE 2017: OECD INDICATORS 180, 180 (2017), https://www.oecd-ilibrary.org/docserver/health_glance-2017-66-en.pdf?expires=1530722899&id=id&accname=guest&checksum=635387EB7ED8A072A3A814979C353E00 (noting that Finland, Sweden, the Netherlands, and Iceland have caesarian rates between 15 and 17%).

245. *Infant Mortality Rates*, OECD, <https://data.oecd.org/healthstat/infant-mortality-rates.htm> (last visited Mar. 25, 2019).

246. See WHO et al., *Maternal Mortality Ratio (Modeled Estimate, Per 100,000 Live Births)*, WORLD BANK (2015), <https://data.worldbank.org/indicator/SH.STA.MMRT>.

247. See, e.g., Diaz-Tello, *supra* note 241, at 222–25; Purvis, *supra* note 238, at 397–402; see also Ehrenreich, *supra* note 243, at 500–01 (discussing the intersection of race and gender as it relates to forced cesarean sections); Law, *supra* note 232, at 359 (“In short, women who have had C-sections are commonly denied the freedom to choose vaginal delivery for subsequent births, even though the medical evidence suggests that the choice is complex, but reasonable.”).

248. Law, *supra* note 232, at 359.

249. Ehrenreich, *supra* note 243, at 501 (“The pattern of behaviors it identifies could occur during any woman's labor, and yet the vast majority of court-ordered C-sections have involved poor women of color.”); Danielle Thompson, *Midwives and Pregnant Women of Color: Why We Need to Understand Intersectional Changes in Midwifery to Reclaim Home Birth*, 6 COLUM. J. RACE & L. 27, 38 (2016).

purported to help them. Like placentophagy, women are historically both the exclusive consumers and providers of midwifery services. In 1900, more than half of American women gave birth through a midwife; by 1950, 88% of women delivered in a hospital.²⁵⁰ State regulation played a huge role in this change, and many have criticized this development as constituting the “medicalization” of childbirth—the paradigm shift that changed the perception of birth as a natural process to a pathology requiring medical intervention.²⁵¹ One of the main culprits of this change was states’ criminalization of the unlicensed practice of medicine around the turn of the century.²⁵² Although the alleged aim of licensing laws was to protect the public, the laws also allowed physicians to reduce the number of providers competing for clients, thereby increasing demand for their services.²⁵³ And physicians, largely due to this anti-competitive motivation, began to sue midwives under licensing laws to increase their customer base.²⁵⁴ This undoubtedly contributed to the mass migration towards hospital labor.²⁵⁵

As a result, childbirth quickly changed from a women-centered ritual where “women wanted and needed only each other”²⁵⁶ to a male-

250. Stacey A. Tovino, *American Midwifery Litigation and State Legislative Preferences for Physician-Controlled Childbirth*, 11 CARDOZO WOMEN’S L.J. 61, 67 (2004).

251. Wolfson describes the “medicalization” of birth as referring to three phenomena: “first, the elimination of the midwife as a primary birth attendant; second, the shift in the location of birth from home to hospital; and third, the use of increasingly invasive medical interventions during the birth process.” Charles Wolfson, *Midwives and Home Birth: Social, Medical, and Legal Perspectives*, 37 HASTINGS L.J. 909, 909 n.3 (1986) (internal citations omitted); see also Purvis, *supra* note 238, at 396.

252. See Thompson, *supra* note 249, at 32.

253. See Susan Corcoran, *To Become A Midwife: Reducing Legal Barriers to Entry into the Midwifery Profession*, 80 WASH. U. L.Q. 649, 656–57 (2002) (“The primary justification for licensure is protection from unqualified, incompetent practitioners. However, licensure of midwifery, as in all professions, also often serves an anticompetitive purpose.”); Walter Gellhorn, *The Abuse of Occupational Licensing*, 44 U. CHI. L. REV. 6, 11 (1976) (“[L]icensing has been eagerly sought—always on the purported ground that licensure protects the uninformed public against incompetence or dishonesty, but invariably with the consequence that members of the licensed group become protected against competition from newcomers.”).

254. See, e.g., Tovino, *supra* note 250, at 85, 101–03; Thompson, *supra* note 249, at 33–35.

255. See Thompson, *supra* note 249, at 32 (describing the shift in the early twentieth century towards hospital births).

256. *Id.* at 30 (“Pre-hospital birthing was thus something of a feminist endeavor in which women wanted and needed only each other, because they knew that their specific female experience made them more equipped than any male physician to aid a woman in a non-complicated labor and delivery.”).

dominated enterprise. “As hospital births grew in prominence and male physicians began to attend more births, the ‘presence of this male authority figure changed the power structure in the [birthing] room.’ This anti-feminist power shift denied women—who were already seen as socially inferior and less capable than men—authority over their own bodies and births.”²⁵⁷ Although delivering in a hospital with the assistance of an OBGYN has many benefits and may be the only feasible option for complicated pregnancies, many women can safely deliver with a midwife either at home, in a birthing center, or at a hospital.²⁵⁸

Women who consume their placentas discuss their aversion to the medicalization of birth, which they often associate with patriarchal overtones.²⁵⁹ Elizabeth Dickinson and her collaborators collected stories of women who participated in placentophagy to understand their motivations. She noted that “[m]ost of the supporters see obstetrics as a dysfunctional childbirth model that disciplines the female body and causes risk to mother and child.”²⁶⁰ For instance, one supporter lamented the “othering of women’s bodies where we make everything gross—breastfeeding, menstruation, birth—it’s all gross.”²⁶¹ Another criticized a reality in which “[m]ost of OBGYNs are men; women aren’t in charge of birth anymore.”²⁶² In collecting these women’s stories, Dickinson concluded that “supporters have come to reject what Foucault (1989) called the ‘medical gaze,’” where “health care professionals (mostly male doctors) in hospitals began to exert power and central authority over the body, relying on empirical observations and analyses to ‘treat’ the body, often regardless of what patients think or want.”²⁶³ She observed that women reject the medicalization of childbirth—including the disgust with placentophagy—as a way of empowering themselves and regaining control over their bodies.²⁶⁴ These women are seeking to exercise their autonomy in a system that has increasingly limited their choices.

257. *Id.* (internal citation omitted) (alteration in original).

258. *See, e.g.,* Jessica Brown, *The Fight for Birth: The Economic Competition That Determines Birth Options in the United States*, 52 U.S.F. L. REV. 1, 6–8 (2018); Ruth Zielinski et al., *Planned Home Birth: Benefits, Risks, and Opportunities*, 7 INT’L J. WOMEN’S HEALTH 361, 375 (2015).

259. Dickinson et al., *supra* note 35, at 123–24.

260. *Id.* at 121.

261. *Id.* at 123.

262. *Id.* at 121.

263. *Id.* at 123.

264. *See id.* at 124 (“The resistance to acting appropriately as per the tenants of patriarchal Western medicine and the medical gaze (e.g., give birth in a hospital, do what the obstetrician tells you, and certainly do not eat your placenta) can be

Some may criticize these women for finding benefit in a product that has no proven effect, for essentially being fooled by a placebo. But this observation is misguided and inherently gendered in this context. The placebo effect itself can produce very strong improvements, and it is not uncommon for physicians to proscribe safe, but unproven, interventions they hope might benefit the patient, especially when traditional treatments have failed.²⁶⁵ Consumers frequently use products or interventions that have no proven benefit over placebo, including acupuncture and supplements.²⁶⁶ But as they are safe, the government does not prevent consumers from indulging in the fantasy to their benefit. In fact, the government has at times gone further and even supported certain placebos, like providing battleground acupuncture for pain management in soldiers.²⁶⁷ Encapsulated placenta is no different, and treating it otherwise creates a double standard for placebo products that only women consume.

FDA has previously been criticized for creating a separate standard for products that only women use and that relate to reproduction. In 2013, the Eastern District of New York chastised FDA for failing to approve Plan B contraception for girls under seventeen without any scientific basis: “Because the Secretary’s action was politically motivated, scientifically unjustified, and contrary to agency precedent, it cannot provide a basis to sustain the denial of the Citizen Petition.”²⁶⁸ This case concluded a years-long struggle with

empowering because mothers can exert control by doing what they want with their placentas, regardless of ‘lack of proof.’”)

265. See, e.g., *The Power of the Placebo Effect*, HARV. MEN’S HEALTH WATCH (May 1, 2017), <https://www.health.harvard.edu/mental-health/the-power-of-the-placebo-effect>; Felicity L. Bishop, Lizzi Aizlewood, Alison E.M. Adams, *When and Why Placebo-Prescribing Is Acceptable and Unacceptable: A Focus Group Study of Patients’ Views*, 9 PLOS ONE 1, 7 (2014) (“[A placebo might relieve [the patient’s] pain when nothing else is available to do that.”); P. Lichtenberg, U. Heresco-Levy & U. Nitzan, *The Ethics of the Placebo in Clinical Practice*, 30 J. MED. ETHICS 551, 552 (2004).

266. See, e.g., David Colquhoun & Steven P. Novella, *Acupuncture Is Theatrical Placebo*, 116 ANESTHESIA & ANALGESIA 1360, 1360 (2013) (“[A]cupuncture quickly became popular in the West . . . [although] the benefits of acupuncture are likely nonexistent, or at best are too small and too transient to be of any clinical significance. It seems that acupuncture is little or no more than a theatrical placebo.”); Nicholas Bakalar, *Placebo Beats Supplements for Arthritis Pain*, N.Y. TIMES (Jan. 26, 2017), <https://www.nytimes.com/2017/01/26/well/live/placebo-beats-supplements-for-arthritis-pain.html>.

267. See e.g., Alex Berezow, *Acupuncture: Is It Ethical to Give a Combat Soldier a Placebo for Pain?*, AM. COUNCIL ON SCI. & HEALTH (Apr. 16, 2018), <https://www.acsh.org/news/2018/04/16/acupuncture-it-ethical-give-combat-soldier-placebo-pain-12846>.

268. *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 192 (E.D.N.Y. 2013); see also *Tummino v. Torti*, 603 F. Supp. 2d 519, 546 (E.D.N.Y. 2009), amended sub nom by

the recalcitrant agency determined to prevent minors from accessing Plan B despite lacking any legitimate safety concerns.²⁶⁹ And now, the ACLU is suing the agency for not letting pharmacies in rural locations provide abortion pills; instead, patients must obtain them at a medical facility.²⁷⁰ The agency has also been accused of prioritizing fetal over maternal harms in how it regulates the labels of pharmaceuticals that might be consumed in pregnancy.²⁷¹ The agency should take care to avoid another instance in which it overregulates women's reproductive choices. If FDA regulates encapsulated placenta to the point it disappears from the market, it will perpetuate the experience of consumers who already feel that women's autonomy over their reproductive decisions is curtailed by governmental and institutional forces that they associated with the patriarchy.

Of course, even the strictest proponents of female autonomy do not oppose all regulations surrounding reproduction and childbirth—women cannot make informed, autonomous decisions when providers, manufacturers, or institutions are not held to a minimum floor of honesty and competence. The medical setting involves an information asymmetry that can make all individuals, including women, vulnerable without some government involvement.²⁷² Pamela Laufer-Ukeles resists the perception that autonomy and protection are mutually exclusive.²⁷³ Instead, she argues that we should “facilitat[e] women's choices within the context of some legislative limits”—in other words, regulations need to promote autonomy by both maximizing choice and minimizing exploitation.²⁷⁴ Her approach recognizes the failures of two different feminist critiques of government regulation (or lack thereof):

Those who have previously examined or attempted to improve women's autonomy in reproductive decision making in the

Tummino v. Hamburg, 936 F. Supp. 2d (E.D.N.Y. 2013) (“Indeed, the evidence strongly suggests that even the decision to permit the OTC sale of Plan B to women over the age of 18 was made solely to facilitate the confirmation of Dr. von Eschenbach as Commissioner of the FDA.”).

269. *Tummino v. Hamburg*, 936 F. Supp. 2d at 164.

270. Sarah McCammon, *ACLU Sues to Increase Access to Abortion Pill*, NPR (Oct. 3, 2017), http://www.npr.org/2017/10/03/555310966/aclu-sues-to-increase-access-to-abortion-pill?utm_source=facebook.com&utm_medium=social&utm_campaign=npr&utm_term=nprnews&utm_content=202703.

271. Donley, *supra* note 46, at 68–75.

272. See Diaz-Tello, *supra* note 241, at 210 (“[T]he provider-patient relationship is one that is characterized by an asymmetry of information and power.”).

273. Laufer-Ukeles, *supra* note 232, at 572.

274. *Id.*

medical context have attacked from one of two directions. One approach is to emphasize the rights of the woman as an individual, irrespective of the fetus. . . .

Others attack reproductive choices as being too unregulated and urge an increase in legislation to improve the safety and health of gestating women. . . .

...

. . . On the one hand, leaving women alone does not do enough to support autonomy. On the other hand, regulating and restricting those choices can go too far in undermining autonomy.²⁷⁵

Laufer-Ukeles's assessment is well taken. Respecting women means neither under nor over regulating them. Women deserve protection without paternalism.

When it comes to the regulation of encapsulated placenta, FDA should aim for a middle ground approach where women benefit from a regulatory floor that mitigates the risk of misinformation and contaminated products, but that ultimately protects women's autonomy to make decisions over their own childbirth experience. This approach would ensure that encapsulated placenta providers are not, for instance, surreptitiously mixing women's placentas together or processing placentas in unsanitary conditions; however, it would not regulate the product so stringently that the small businesses could not comply with the regulations, driving encapsulated placenta from the market entirely.

* * *

Both policy concerns discussed in this Part suggest that regulation of encapsulated placenta is warranted, but not so much as to render to product unavailable. Taking these considerations into account would ask the agency to regulate the product according to a category that both establishes a minimum floor with regard to risk, but also ensures the product's availability. In Part IV, I argue that Intended Use would produce a bad result from a policy perspective—it would lead to the product's under or overregulation. In such cases, FDA will occasionally use its enforcement discretion to regulate the product in a manner that best protects consumer safety and access. I think it should do so here. I argue below that FDA should regulate encapsulated placenta as both a 361 HCT/P and a supplement. Such

275. *Id.* at 571–73.

regulation would best effectuate the policy goals underlying FDA categories and balance FDA's competing priorities. It would be a novel categorization—I do not know of any other product regulated under these two categories—but one that the agency might use for various other new technologies involving biologic substances that do not require premarket review to protect consumers.

IV. TOWARD A BALANCED REGULATION OF ENCAPSULATED PLACENTA

FDA's typical mechanism for classifying mixed products—Intended Use—would create a problematic result in the case of encapsulated placenta. Either it would classify encapsulated placenta as a drug or biologic, which would overregulate it to the point that it disappears from the market, or as a supplement, which would fail to prevent the types of harms that encapsulated placenta has recently caused. I argue below that FDA should use its enforcement discretion to regulate encapsulated placenta as both a supplement and a 361 HCT/P. These regulations combined would ensure that women are protected from the worst risks of encapsulated placenta—unsubstantiated disease claims and the improper processing of tissue—without creating insurmountable entry barriers for the product. It therefore strikes an appropriate balance in protecting women without eliminating their choices.

A. Intended Use Would Lead to the Wrong Result

As explored in Section II.B, Intended Use does not produce clear results for encapsulated placenta. Under the most likely scenario, FDA would find that encapsulated placenta is a human tissue that fails to meet the 361 HCT/P requirements and must therefore be regulated as a biologic requiring premarket review. It's possible, however, that if encapsulated placenta manufacturers were marketing their products as supplements without making disease claims, FDA would only require them to meet the supplement regulations. This is the approach the agency appears to be taking (at least in the short term) for probiotics, which should also technically be regulated as biologics under FDA's regulatory scheme.

Neither of these options, however, would create the optimal outcome from a policy perspective. Supplement regulations would underregulate the product, opening women up to unnecessary risks. Though supplement regulations prevent the type of harm associated with unsubstantiated disease claims, they would fail to prevent the types of harms associated with improper handling of human tissue.

For instance, the supplement regulations would not stop manufacturers, like the ones in Miami, from mixing various women's placentas together before distributing them.²⁷⁶ They would also not stop manufacturers from undercooking the product and causing bacterial infections like the one the CDC reported.²⁷⁷ And it would not stop the cross contamination of tissues that might lead to a spread of diseases like HIV, Zika, and hepatitis.²⁷⁸ Human tissues are not vitamins; processing them involves compliance with particular conditions that reduce contamination risks.²⁷⁹ As a result, supplement regulations alone are insufficient.

On the other hand, the biologic regulations, which require premarket review, will overprotect women to their detriment. Encapsulated placenta, like most supplements, would be unable to benefit from either patent or regulatory exclusivity.²⁸⁰ Thus, if it were regulated as a drug or biologic, the regulation would act as an effective ban as manufacturers would have no incentive to incur the cost associated with new drug or biologic approval.²⁸¹ And exclusivity would not make sense for encapsulated placenta. Unlike most drugs and supplements, which can be mass-produced and sold nationally under a monopoly, encapsulated placenta can only be safely made

276. See *Florida Department of Health*, *supra* note 67.

277. Buser et al., *supra* note 65, at 677.

278. Farr et al., *supra* note 2, at 405.

279. See *id.*

280. Because the product is already on the market, manufacturers could not meet the novelty requirement for patent protection. See Abbott, *supra* note 193, at 68–73. And while encapsulated placenta manufacturers could apply for FDA's regulatory exclusivity if it were approved as a new drug, FDA has generally chosen to not enforce that exclusivity for products already on the market. See Sachs & Edelman, *supra* note 121, at 404. To explain why the lack of exclusivity matters, consider this explanation from Eisenberg: If FDA were to tell the placentophagy industry that it must obtain premarket approval, encapsulated placenta would be removed from the market until the industry produced sufficient research to demonstrate "it [was] safe and effective." Eisenberg, *supra* note 97, at 379 (describing a similar hypothetical). But encapsulated placenta is not patentable or guaranteed regulatory exclusivity. Thus, even if a manufacturer funded the research that proved encapsulated placenta's safety and efficacy, it would re-enter the market without a monopoly and every other placentophagy manufacturer (none of whom shared in the cost of the research) could use the new data to promote their product. In this scenario, the manufacturer would not be able to recoup any of the money it spent on the research, and competition could still drive it out of business. Furthermore, the funded study might actually show that encapsulated placenta is "unsafe," or more likely, "ineffective." Then, the manufacturer would lose the money it invested in research, fail to obtain FDA approval, and still be forced to exit the market. Manufacturers would therefore have nothing to gain by funding the research and attempting to gain drug approval and would instead accept that they were forced out of the market. See *id.*

281. Eisenberg, *supra* note 97, at 379.

individually. It is a product made from a woman's own tissue, and as a result, if one manufacturer received exclusivity, it could not take advantage of it by cornering the national market. Rather, exclusivity in this context would only function to make the product available to the women within physical proximity to the exclusive provider.²⁸² Premarket review is simply an ill-fitting scheme for this product.

Of course, if encapsulated placenta raised serious safety concerns, it should be inaccessible. But as I argue below, FDA can remove the safety risks while maintaining the product's accessibility. Creating the ideal solution involves examining the product's genuine risks and narrowly tailoring regulations to neither over- nor under-protect women. Below, I explore the risks of encapsulated placenta and the regulations designed to prevent those exact risks. I conclude that the supplement and 361 HCT/P regulations combined would sufficiently protect women without removing access.

B. FDA Should Use Its Discretion to Regulate Encapsulated Placenta as Both a Supplement and 361 HCT/P

The main types of harms that encapsulated placenta risks are (1) the spread of communicable diseases caused by the improper handling of human tissue, and (2) unsubstantiated disease claims. These are the types of harms that the 361 HCT/P and supplement regulations are designed, respectively, to prevent. Furthermore, because encapsulated placenta contains a new dietary ingredient, regulating it as a supplement would also ensure that it meets minimum safety standards. Neither of these regulations, however, require the intense premarket review of drug or biologic regulations (and the corresponding efficacy requirements), and as a result, would not cause the product to disappear from the market. For FDA to regulate encapsulated placenta in this way, it would need to exercise its enforcement discretion, which it has done in the past for similarly novel products. To effectuate the policy concerns discussed in Part III, the agency should take the same approach here.

282. This inability to "scale up" is one of the things that has led to the more minimal regulations for blood and fecal transplants. Sachs & Edelstein, *supra* note 121, at 409, 414.

1. The 361 HCT/P and Supplement Regulations Would Adequately Protect Consumers

The best way to protect consumers from a particular product without overprotecting them is to match a product's risks with regulations intended to mitigate those exact risks. This approach would not work when a product's risks are unknown, but given that encapsulated placenta has been on the market for decades (and recently studied in the literature), we have some confidence in our knowledge of its risks—namely, the spread of communicable diseases and unsubstantiated claims about the product's ability to treat or prevent disease.²⁸³ The 361 HCT/P and supplement regulations are aimed at mitigating those specific risks without requiring premarket approval, and therefore regulating encapsulated placenta under these categories should strike the appropriate balance between FDA's competing goals.

a. Improperly Handled Tissue

As discussed in Part I, there are risks associated with improperly prepared placenta, including the spread of communicable disease. First, as highlighted by the CDC report, when placentophagy providers fail to properly store and heat the placenta, it can contain harmful bacteria that may cause infections in either the mother or breast-feeding infant.²⁸⁴ Second, providers working with multiple placentas may fail to properly separate the tissues and sanitize their instruments, which can result in the spread of viruses between the placentas, like HIV, hepatitis, and Zika.²⁸⁵ Third, providers could mix different women's tissues in a mass production scheme, like the plot FDA foiled in Miami in 2008.²⁸⁶

The 361 HCT/P regulations seek to prevent the spread of communicable diseases, including those transmitted by bacteria and viruses.²⁸⁷ They require manufacturers to abide by donor eligibility requirements, like donor screening and testing, when the donor is different from the recipient; follow good tissue practices that prevent spoliation, contamination, and the spread of communicable diseases; and ensure that all manufacturers have registered with FDA so that

283. See *supra* text accompanying notes 62–77.

284. See Part I; Buser et al., *supra* note 65, at 677.

285. Farr et al., *supra* note 2, at 405.

286. See Part I; Florida Department of Health, *supra* note 67.

287. 21 C.F.R. § 1271.150(a) (2018).

the agency can inspect for compliance.²⁸⁸ FDA has stated that the primary purpose of these regulations is to increase “public confidence in [HCT/P] safety, by preventing the introduction, transmission and spread of communicable disease.”²⁸⁹

In particular, 361 HCT/P regulations require manufacturers to “recover, process, store, label, package, and distribute HCT/Ps . . . in a way that prevents the introduction, transmission, or spread of communicable diseases.”²⁹⁰ HCT/Ps must be stored “at an appropriate temperature.”²⁹¹ These requirements would ensure that placentophagy providers (1) properly refrigerate the tissue until it is ready for processing to prevent spoliation and (2) properly heat the placenta to temperatures necessary to kill sufficient bacteria to prevent the spread of bacterial infections. These two precautions alone would help prevent infections like the one CDC reported.²⁹²

Furthermore, any “establishment that processes HCT/Ps” must do so “in a way that does not cause contamination or cross-contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P.”²⁹³ The facility must also “establish and maintain procedures for cleaning, sanitizing, and maintaining equipment to prevent malfunctions, contamination or cross-contamination . . .”²⁹⁴ These regulations would ensure that placentophagy providers keep tissues separated and sanitize any instruments or surfaces that come into contact with multiple tissues. Finally, the 361 HCT/P regulations also specifically prevent tissue pooling: “Human cells or tissue from two or more donors must not be pooled (placed in physical contact or mixed in a single receptacle) during manufacturing.”²⁹⁵ This regulation would prevent the mass placenta encapsulation schemes, like the one in Florida FDA foiled in 2008.²⁹⁶ Taken together, the 361 HCT/P regulations could prevent the risk of communicable disease that encapsulated placenta presents. The product should therefore be regulated under this scheme.

288. *Id.* § 1271.

289. FDA, REGULATION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS), *supra* note 147, at 3.

290. 21 C.F.R. § 1271.145 (2018).

291. *Id.* § 1271.260(b); *see also* 21 C.F.R. § 1271.260(e) (2018).

292. *See* Buser et al., *supra* note 65, at 677.

293. 21 C.F.R. § 1271.220(a) (2018).

294. *Id.* § 1271.200(b).

295. *Id.* § 1271.220(b).

296. *See Florida Department of Health, supra* note 67.

b. Unsubstantiated Disease Claims

Another risk of encapsulated placenta is that manufacturers will make unproven disease claims in marketing their products. The supplement regulations recognize that disease claims are special and should not be made without first having their accuracy scrutinized through premarket review. FDA has concluded that disease claims “can pose serious risks to consumers” by inducing them “to substitute ineffective or less effective treatments for proven ones, especially if the disease involved is serious or life-threatening.”²⁹⁷ A product’s claims that it will prevent cancer, cure osteoporosis, treat heart disease, or mitigate the symptoms of depression meet consumers where they are most vulnerable, seriously influencing purchasing decisions.²⁹⁸ As a result, FDA worried that “patients cannot safely evaluate on their own” the “claims that might relate to serious health conditions.”²⁹⁹ To prevent manufacturers from taking advantage of consumers’ often desperate desire to fix the pain and suffering caused by disease, the agency only allows disease claims when their accuracy has been proven through premarket review of new drugs and biologics.³⁰⁰

Structure, function, and nutrient deficiency claims, by contrast, are general statements about how supplements may affect the human body. The claims that, for instance, soluble fiber improves the functioning of the digestive tract; that calcium builds strong bones; or that iron helps with an iron deficiency do not make the kinds of promises that consumers might be desperate to hear. Furthermore, consumers are less likely to interpret the statements as directed specifically at them—unlike structure, function, and nutrient deficiency claims, disease claims are more individualized to consumers who have been diagnosed with a particular condition. Given the important distinctions between these two types of claims, the supplement regulations permit structure, function, and nutrient deficiency claims to appear on supplement labels.³⁰¹

297. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000) (to be codified at 21 C.F.R. pt. 101).

298. See Gilhooley, *Herbal Remedies*, *supra* note 130, at 687.

299. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body 65 Fed. Reg. at 1011 (Jan. 6, 2000) (to be codified at 21 C.F.R. pt. 101).

300. See *id.* at 1023.

301 Nevertheless, a manufacturer can only make structure, function, or nutrient deficiency claims if it has substantiation that the claim is truthful and not misleading. This evidentiary standard is notably less stringent than what is required to prove

Like supplement manufacturers, encapsulated placenta manufacturers should be prohibited from making disease claims unless the manufacturers can prove efficacy through premarket review. Placenta products that make disease claims should be taken off the market. The most common disease claim that encapsulated placenta manufacturers make is that the product can treat or mitigate the symptoms of post-partum depression or post-partum mood disorders. This claim is concerning. Very little evidence beyond self-reporting demonstrates that encapsulated placenta is more effective than placebo at causing any purported benefit.³⁰² And though placebo can be quite powerful,³⁰³ it could also cause women with serious post-partum depression to forgo pharmacological treatment.³⁰⁴ Untreated postpartum depression can cause serious physical and emotional harm to both the mother and child.³⁰⁵ This is exactly the type of disease claim that comes with serious risks and should not be made by encapsulated placenta manufacturers unless future research clearly corroborates it. To the extent that manufacturers want to market encapsulated placenta with structure, function, or nutrient deficiency claims, however, they may do so as long as they follow FDA's guidelines, including that the claim be substantiated and properly disclaimed.³⁰⁶

c. Minimum Safety Assurances

Finally, supplement regulations would also ensure a minimum standard of safety. Because encapsulated placenta was not on the market in 1994 and is not currently in the food supply, the dietary supplement regulations would require manufacturers to obtain new

accuracy of disease claims under premarket review, which reflects the reduced risk that structure, function, and nutrient deficiency claims will induce irrational decision-making or be beyond the ability of consumers to evaluate. *Guidance for Industry: Structure/Function Claims*, *supra* note 128.

302 See Young, *Pilot 2*, *supra* note 57, at e268.

303 See *supra*, Section III.B; Selander et al., *supra* note 8, at 105.

304 See, e.g., Bakalar, *supra* note 266.

305 See, e.g., Shelley Doucet et al., *Differentiation and Clinical Implications of Postpartum Depression and Postpartum Psychosis*, 38 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 269, 269-70 (2009) ("If left untreated, both disorders can result in negative consequences including the risk of recurrent psychiatric illness, marital dysfunction, suicide, and infanticide. Research on PPD has shown that the infant is at risk for behavioral problems, delayed cognitive or psychosocial development, and impaired mother-infant bonding." (internal citations omitted)).

306 See Section II.A.2.

dietary ingredient approval.³⁰⁷ Unlike premarket review, which takes decades to prepare the research necessary for a successful application, an NDI application must only be submitted seventy-five days before the product enters the market.³⁰⁸ Once those seventy-five days have passed, the product can be marketed unless FDA denies the application—in other words, the manufacturer does not need to wait for approval.³⁰⁹

As part of the application process, the manufacturer must demonstrate that it is “reasonably . . . expected to be safe under the conditions of use recommended or suggested in the labeling.”³¹⁰ Encapsulated placenta manufacturers should be able to make this showing.³¹¹ The product has been on the market and consumed safely by women when properly processed for over a decade.³¹² And more, research teams have started conducting studies on women consuming their placentas, none of which have reported adverse events for the women or their children.³¹³ The 361 HCT/P regulations would only make these products safer. Though FDA rejected sheep placenta as an NDI in 2002, the landscape and research has entirely changed in the past fifteen years, and with only minimal effort, an encapsulated placenta manufacturer could submit an application that was of much higher quality than the one FDA reviewed in 2002.³¹⁴ Of course, if new evidence were to emerge suggesting that properly processed encapsulated placenta presented serious safety concerns, it would call into question the assumptions of this Article, and the agency should deny NDI approval.

In combination, the 361 HCT/P and supplement regulations should adequately protect women and their children without overregulating a product they exclusively produce and consume. The

307. Manufacturers would need to prove that placenta is a “a dietary substance for use by man to supplement the diet by increasing total dietary intake,” likely pointing to the vitamins and minerals it contains. *New Dietary Ingredients*, *supra* note 112.

308. *Id.*

309. *Id.*

310. *Id.*

311. Of course, the outcome is not predetermined, nor should it be. If FDA cannot conclude that the product meets minimum safety standards, then the product should not be sold.

312. *See supra* Part I.

313. *See supra* Part I.

314. *See* NDI 139 - Sheep Placenta from YAT CHAU (USA) INC., *supra* note 117, at 1–2 (listing the reasons why the proposal was rejected in 2002). As noted above, FDA’s letter explained that the applicant failed to comply with the basic requirements of the application process.

361 HCT/P regulations will require placentophagy providers to abide by processing standards that will protect women from the risks associated with the spread of communicable diseases.³¹⁵ The supplement regulations will ensure that providers are not making risky and unsubstantiated disease claims that might cause women to forgo needed treatment. They will also establish a minimum level of safety. This scheme would both protect women without paternalistically deciding what is best for them. Obtaining this outcome, however, is only possible if FDA uses its discretion to regulate the product outside of its typical statutory scheme. Without such enforcement discretion, FDA would be required to follow its own standards and regulate the product according to Intended Use (as discussed in Sections II.A and IV.A).

2. FDA Can (and Should) Use Its Enforcement Discretion to Achieve This Result

FDA occasionally uses its enforcement discretion to regulate products less stringently than its regulations require. If premarket review is too harsh for a particular product, it can decline to enforce those regulations;³¹⁶ or if a disease claim has been sufficiently proven for a particular supplement, it can decline to enforce the supplement regulations' prohibition of disease claims.³¹⁷ In so doing, the agency will publish on its website a Guidance for Industry, which describes its enforcement policy for a particular product.³¹⁸ Here, enforcement discretion would allow the agency to define the product as both a supplement and a 361 HCT/P. In other words, the agency would be declining to enforce the full biologic regulations, which are required for human tissues that do not meet the elements of Section 1271.10.³¹⁹ Although FDA has never regulated a product under these two

315. See 21 C.F.R. § 1271 (2018).

316. See e.g., FDA, ENFORCEMENT POLICY, *supra* note 224, at 2 (“[A]n IND sponsor may request a waiver of certain IND regulations applicable to investigators for those licensed health care providers receiving FMT product to treat patients with *C. difficile* infection not responsive to standard therapies.”).

317. See, e.g., Letter from Barbara O. Schneemann, Dir., Office of Nutrition & Dietary Supplements, to Jonathan W. Emord, (June 19, 2009) (archived at <https://wayback.archive-it.org/7993/20171101205421/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm168527.htm>).

318. See, e.g., *Summary of Qualified Health Claims Subject to Enforcement Discretion*, *supra* note 168; FDA, ENFORCEMENT POLICY, *supra* note 224, at 1.

319. See 21 C.F.R. § 1271.10 (2018).

categories before, it does regulate certain products under two different categories.³²⁰

The Supreme Court has unequivocally upheld FDA's ability to decline to enforce its provisions, likening it to a prosecutor's discretion to not bring charges against a criminal defendant.³²¹ One benefit of enforcement discretion is its flexibility.³²² FDA can change its mind if new facts surface indicating that such discretion is no longer warranted, for instance, if the product is revealed to be more dangerous than expected. This is particularly useful for encapsulated placenta, where the research on the product is only beginning and our understanding of the product's safety could change.

FDA has recently exercised enforcement discretion for a product that threatened similar outcomes if it had been overregulated. As previewed in Part III, the example is processed, donated stool for fecal transplants to treat *C. difficile* infections.³²³ Unlike encapsulated placenta, which might only be providing a placebo benefit, fecal transplants have been remarkably effective.³²⁴ But like encapsulated placenta, they suffer from a categorization problem: what exactly is processed feces?³²⁵ The agency determined initially that the donated stool constituted a combination drug-biologic product and would need to obtain premarket review.³²⁶ But after "physicians and scientists expressed concern" that the regulations "would make [fecal transplants] unavailable," FDA decided to not enforce its regulations so long as certain conditions were met, including the recipient's

320. See, e.g., *Is It a Cosmetic, Drug, or Both? (Or Is It Soap?)*, FOOD & DRUG ADMIN. (Aug. 22, 2018), <https://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074201.htm>.

321. *Heckler v. Chaney*, 470 U.S. 821, 832 (1985).

322. But see, e.g., Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 117–18 (2014). In fact, some argue that enforcement discretion creates lawlessness at an agency because the agency can create and rescind decisions without any process. *Id.* ("When the statutory provision sunset in 2006, the FDA opted to rescind rather than amend the implementing regulation, which it then replaced with a substantially similar (though, of course, technically nonbinding) guidance document.").

323. FDA, ENFORCEMENT POLICY, *supra* note 224, at 2.

324. See Sachs & Edelstein, *supra* note 203, at 401 ("[Physicians and scientists] argued that the available evidence supporting FMT's effectiveness as a therapy for refractory *C. difficile* infection was too compelling for regulators to restrict its availability to the treatment groups of clinical trials.").

325. Bethany Brookshire, *To Regulate Fecal Transplants, FDA Has to First Answer a Serious Question: What Is Poop?*, SCIENCE DAILY (May 18, 2018), <https://www.sciencenews.org/blog/scicurious/fecal-transplants-regulation> ("The first problem is to figure out what an FMT actually is, at least, in terms of how the government should regulate one.").

326. FDA, ENFORCEMENT POLICY, *supra* note 224, at 1 n.1.

consent and the screening of the donated stool, which cannot come from a stool bank.³²⁷ According to FDA, it “developed this [enforcement discretion] policy to assure that patients with *C. difficile* infection not responding to standard therapies may have access to this treatment, while addressing and controlling the risks that centralized manufacturing in stool banks presents to subjects.”³²⁸ The approach advocated for in this Article is slightly different in that it would have FDA regulate a product according to two different categories—one of which the product does not clearly meet the definition: 361 HCT/P regulations. Though this is a novel recommendation, if FDA can regulate a product under harsher regulations (human tissue biologics), it should be able to exercise its discretion to regulate the product under a less onerous subset of those regulations (361 HCT/Ps).

There are many commonalities between fecal transplants and encapsulated placenta that might encourage the agency to similarly invoke its enforcement discretion. First and foremost, like encapsulated placenta, the agency was concerned that regulating donated feces as a drug would obliterate access. Fecal transplants, like placentophagy, are already widely available,³²⁹ making the incentives of exclusivity a poor motivator.³³⁰ Also like encapsulated placenta, donated stool presents difficulties in scaling up—i.e., even if exclusivity were granted, it’s unclear how a single provider could meet nationwide demand.³³¹ Because both products are made from donated (or self-donated) human waste, creating a national market is not as straightforward as products that are made in labs and can be easily scaled up and mass produced.³³² In fact, FDA decided to exercise its enforcement discretion after a public outcry that premarket review would effectively ban the intervention entirely.³³³

As previewed in Part III, encapsulated placenta and fecal transplants share another similarity: the risk that overregulation, by driving manufacturers from the scene, would create a do-it-yourself

327. *Id.* at 2–3.

328. *Id.* at 2.

329. Megan Molteni, *Patients Want Poop Transplants. Here’s How to Make Them Safe*, WIRED (Dec. 14, 2017, 2:00 PM), <https://www.wired.com/story/patients-want-poop-transplants-heres-how-to-make-them-safe/> (“Today, 98 percent of the US population lives within two hours of a fecal transplant provider.”).

330. See Sachs & Edelstein, *supra* note 203, at 403–06 (discussing the history of exclusivity issues as well as those issues as related to FMTs).

331. *Id.* at 414.

332. *Id.* at 409.

333. FDA, ENFORCEMENT POLICY, *supra* note 224, at 2–3; Sachs & Edelstein, *supra* note 203, at 400–01.

industry that is more harmful than the status quo. Fecal transplant advocates raised this exact concern in arguing for enforcement discretion from the premarket review regulations: “patients may resort to essentially free at-home transplantations, using friends or family members, screened at the patient’s discretion, as donors.”³³⁴ Of course, “[u]nsupervised, do-it-yourself treatments carry considerable risk of the transmission of pathogens from improperly screened and handled stool.”³³⁵ Any regulatory scheme that would remove encapsulated placenta from the market would create similar safety risks for women, as it is one of the few types of products for which a do-it-yourself industry is easily made. Many women already choose to eat the placenta raw, cook it, or encapsulate it themselves.³³⁶ Placenta that is raw or not properly dehydrated contains potentially dangerous bacteria³³⁷ and is much more likely to cause safety incidents like the CDC report raised. An industry composed of regulated experts that must comply with the supplement and 361 HCT/P regulations is preferable from a safety perspective than unregulated novices. And if women are no longer allowed to buy encapsulated placenta, they will very likely produce the product themselves, outside of FDA’s control.

Finally, FDA regulation will also encourage more placentophagy providers to obtain training and certification. Although today there are already certification and training programs,³³⁸ certification’s only benefit is marketing—the possibility that more women will prefer to buy services from formally trained or certified providers. The motivation for training and certification will dramatically increase once the product is regulated and providers realize that FDA can prosecute them for failing to comply with the 361 HCT/P and supplement regulations. Individual providers, furthermore, will need training to understand and comply with the regulatory requirements. The more that training and certification become integral to placentophagy production, the safer the product will become for women.

An FDA enforcement policy regulating encapsulated placenta as both a supplement and 361 HCT/P is supported by the policy concerns discussed in Part III. It would neither “leav[e] women alone” nor

334. Sachs & Edelstein, *supra* note 203, at 406.

335. *Id.* at 407.

336. *See, e.g.*, Hayes, *supra* note 2, at 79.

337. Johnson, *supra* note 69, at 11 (“Potentially pathogenic organisms (*E. coli*, *Gardnerella vaginalis*) were detected in raw placental tissue but were absent after dehydration.”).

338. *See supra* text accompanying notes 73–74.

“undermin[e their] autonomy” by restricting choices.³³⁹ The women who engage in placentophagy are distrustful of the medical establishment, which they see as a patriarchal institution that undervalues women’s needs and experiences.³⁴⁰ Overregulation of encapsulated placenta would perpetuate these consumers’ feelings that their preferences are being ignored, especially if the regulations effectively banned a safe product they relied upon. After all, the qualitative research suggests that consumers find encapsulated placenta enormously useful, even if the benefits are largely attributed to the placebo effect.³⁴¹ In fact, the tension between access and protection in encapsulated placenta tracks very closely to the debate that led to the enactment of the DSHEA. There too, relatively safe products with unknown benefits were vulnerable to overregulation that could take them off the market. FDA should resolve the tension in favor of access, securing a minimum floor by holding encapsulated placenta to the supplement and 361 HCT/P regulations, which should adequately protect women. Enforcement discretion allows the agency to create that perfectly tailored regulatory scheme.

CONCLUSION

Post-partum consumption of encapsulated placenta is no longer a fringe practice. It comes with significant perceived benefits and also real risks. FDA has not yet waded into the practice, but it should. Without any regulation, providers can (and undoubtedly are) making unsubstantiated promises about the product’s ability to prevent or treat diseases like post-partum depression; some are also undoubtedly processing the placenta in conditions that could lead to cross-contamination and the spread of bacteria. But the solution should not be to regulate the product as a drug or biologic, which would remove from the market a safe product that many women find helpful. Instead, FDA should tailor regulations narrowly to reduce the harms the product risks. The 361 HCT/P and supplement regulations accomplish this goal: they were designed to prevent the spread of communicable disease, to prohibit manufacturers from making unsubstantiated disease claims, and to create a safety floor for new dietary ingredients. Though FDA’s regulatory scheme would not yield this solution on its own, FDA can and should generate this result by exercising its enforcement discretion, as it has done with similar

339. Laufer-Ukeles, *supra* note 232, at 573.

340. Dickinson et al., *supra* note 35, at 121–24.

341. Selander et al., *supra* note 8, at 105.

products. This result would balance FDA's competing goals and ensure that women are neither over- nor under-protected.

