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When Religious Belief Becomes Scientific Opinion: *Burwell v. Hobby Lobby* and the Unraveling of Federal Rule 702

Meredith Rachel Mandell¹

For over 20 years, the federal courts have adhered to a number of rules designed to ensure that only valid and reliable science forms the basis for court decisions. The seminal case is *Daubert v. Merrell Dow Pharmaceuticals*,² in which the U.S. Supreme Court set down the core standards for admissibility of scientific opinions. Those standards later became embodied in Federal Rule of Evidence 702, which reads:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.³

There have been thousands of federal court decisions involving the *Daubert*/Rule 702 standards,⁴ and many state courts now follow the same standards.⁵ A principal goal of Rule 702 is to guard against the danger of “junk science”⁶ tainting decisions that depend on scientific or other specialized knowledge.⁷ Yet, in spite of Rule 702 and its 20-year

¹ J.D., 2016 Northwestern University School of Law. I greatly appreciate the generous help of Fern E. Murdoch, Ph.D., Center for Reproductive Science, Northwestern University, on the scientific sections in this Note. My thanks as well to my editors on the Northwestern Journal of Law and Social Policy for their excellent edits, meaty comments, and patience with the writing process. All errors and omissions are my own. I dedicate this article to my mother, Stephanie Scharf, a lawyer who has been a great mentor to me.

² *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

³ FED. R. EVID. 702.

⁴ WestlawNext shows over 100,000 citing references for both *Daubert* and Rule 702. See Westlaw, next.westlaw.com (last visited Jan. 19, 2016).

⁵ See, e.g., ARIZ. R. EVID. 702; ARK. R. EVID. 702; CONN. CODE EVID. § 7-2; FLA. STAT. §§ 90.702.

⁶ See PETER W. HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM* 2–3, (Basic Books 1991). The author provides a thorough historical and social review of “junk science,” its origins, and its invasion of the American Courtroom.

⁷ See FED. R. EVID. 702 advisory committee's note (2000 amendments) (“Rule 702 has been amended in response to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and to the many cases applying *Daubert*, including *Kumho Tire Co. v. Carmichael*, 119 S. Ct. 1167 (1999). In *Daubert* the Court

history, a recent and highly publicized legal decision, which rested on faulty scientific beliefs, was made without the benefit of a Rule 702 analysis.

The case is *Burwell v. Hobby Lobby*,⁸ in which the Supreme Court held that the contraceptive mandate, a regulation promulgated by the Department of Health and Human Services under the Affordable Care Act (the Act),⁹ substantially burdened the employers' exercise of religion under the Religious Freedom Restoration Act of 1993 (RFRA).¹⁰ The mandate substantially burdened the *Hobby Lobby* employers' religious beliefs because it required the employers to provide access to four specific contraceptives which they believed were abortifacients,¹¹ and the Department of Health and Human Services had not proven the mandate was the "least restrictive means" of furthering a compelling governmental interest.¹²

The Supreme Court made a critical assumption that the four contraceptives at issue were, in fact, abortifacients. But the Court received no scientific evidence, nor did any court below, for the proposition that the challenged contraceptives were actually tantamount to abortions. In essence, the Supreme Court deferred not only to the employers' religious beliefs that abortion is wrong, but also to their erroneous scientific beliefs about whether any of four specific contraceptives constitutes an "abortion."

Such deference became the basis for the Court's decision that the four particular types of contraceptives need not be funded by the *Hobby Lobby* employers. Importantly, neither the *Hobby Lobby* trial courts¹³ nor the *Hobby Lobby* appellate courts¹⁴ required a Rule 702 review of the scientific opinions that were the basis *Hobby Lobby* plaintiffs' position.

The lack of Rule 702 review begs the question: in light of more than 20 years of federal jurisprudence setting the modern standards for the use of reliable and valid science in federal litigation, how can the Supreme Court justify its reliance on a religious belief rather than science for its conclusion about what constitutes an abortion? In essence, the *Hobby Lobby* court permitted junk science to trump access to contraceptives. The decision is all the more troubling in light of the long-established constitutional right of access to contraceptives.¹⁵

In this paper, Part I will review the reasons why Rule 702 exists and what standards are imposed on the admissibility of scientific opinions; Part II will review the decision in

charged trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony, and the Court in *Kumho* clarified that this gatekeeper function applies to all expert testimony, not just testimony based in science.").

⁸ *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct 2751 (2014). The Supreme Court decision encompassed two consolidated cases: No. 13-354, *Sebelius, Sec'y of Health and Human Serv. v. Hobby Lobby Stores*; and No. 13-356, *Conestoga Wood Specialties v. Sebelius*. I will refer to both cases as "*Hobby Lobby*."

⁹ The Patient Protection and Affordable Care Act, 42 U.S.C. § 300gg-13 (2015).

¹⁰ Religious Freedom Restoration Act of 1993, 42 U.S.C. §2000bb et seq. (2015).

¹¹ *Hobby Lobby*, 134 S. Ct. at 2759.

¹² *Id.* at 2757.

¹³ *Hobby Lobby Stores, Inc. v. Sebelius*, 870 F.Supp.2d 1278 (W.D. Okla. 2012); *Conestoga Wood Specialties Corp. v. Sebelius, et al.*, 917 F.Supp.2d 394 (E.D. Pa. 2013).

¹⁴ *Hobby Lobby Stores, Inc. v. Sebelius*, No. 12-6294, 2012 WL 6930302, at *1 (10th Cir. 2012); *Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dept. of Health and Human Serv.*, 724 F.3d 377 (3d Cir. 2013).

¹⁵ See *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

Hobby Lobby and the purported science involved in the case; Part III will review the lack of Rule 702 review by the *Hobby Lobby* lower courts; Part IV will review the scientific debate concerning contraceptives as abortifacients; Part V will consider the admissibility of potentially conflicting scientific opinions in *Hobby Lobby*; and Part VI will examine how scientific evidence could have changed the outcome of the case. In conclusion, I consider the implications of *Hobby Lobby* from the perspective of how courts should resolve factual disputes between scientific knowledge and religious beliefs.

I. RULE 702: ITS PURPOSE AND OPERATION WITH RESPECT TO SCIENTIFIC OPINIONS IN LITIGATION

A. Purpose of Rule 702

The purpose of Rule 702 is to protect the scientific integrity of decisions made in courtrooms by barring “junk science.”¹⁶ As explained by Peter Huber, one of many commentators who castigated the pre-*Daubert* trend of junk science invading the courtroom in high profile litigation cases:

Junk science is the mirror image of real science, with much of the same form but none of the same substance. There is the astronomer, on the one hand, and the astrologist, on the other. The chemist is paired with the alchemist, the pharmacologist with the homoeopathist. Take the serious sciences of allergy and immunology, brush away the detail and rigor, and you have the junk science of clinical ecology. The orthopedic surgeon is shadowed by the osteopath, the physical therapist by the chiropractor, the mathematician by the numerologist and the cabalist ... Junk science cuts across chemistry and pharmacology, medicine and engineering. It is a hodgepodge of biased data, spurious inference, and logical legerdemain, patched together by researchers whose enthusiasm for discovery and diagnosis far outstrips their skill. It is a catalog of every conceivable kind of error: data dredging, wishful thinking, truculent dogmatism, and, now and again, outright fraud.¹⁷

Before the 20th century, courts in the United States did not rigorously examine the reliability of expert testimony.¹⁸ But as the nation leapt forward in the realms of science and technology during the Industrial Revolution, expert scientific witnesses began to

¹⁶ MICHAEL H. GRAHAM, HANDBOOK OF FEDERAL EVIDENCE § 702:5 (7th ed. 2013).

¹⁷ See HUBER, *supra* note 6, at 2–3. Accord JACK KITAEFF, MALINGERING, LIES, AND JUNK SCIENCE IN THE COURTROOM (2007); William Glaberson, *The Nation: Assigning Blame; The Courts Vs. Scientific Certainty*, N.Y. TIMES, June 27, 1999, <http://www.nytimes.com/1999/06/27/weekinreview/the-nation-assigning-blame-the-courts-vs-scientific-certainty.html>.

¹⁸ Janusz Puzniak, *Expert Evidence: The Road from Daubert to Joiner and Kumho Tire*, 37 COURT REV. 32, (Fall 2000) (citing Jack B. Weinstein, *Improving Expert Testimony*, 20 U. RICH. L. REV. 473, 474–75 (1986) [hereinafter Puzniak]).

appear more frequently to testify during trials.¹⁹ As a consequence, legal scholars and practitioners began to think about how best to assess expert testimony.²⁰

In *Frye v. United States*,²¹ where a criminal defendant questioned the admissibility of a systolic blood pressure test as evidence, what was a crude precursor to the polygraph “lie detector” test, the D.C. Circuit ruled that expert testimony must be grounded in established scientific technique or, in other words, the “thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.”²² This *Frye* test or the “general acceptance test” became the common law standard for 70 years, surviving the adoption of the Federal Rules of Evidence until the Supreme Court’s *Daubert* decision in 1993.²³ The *Frye* test required judges first to identify the scientific field of the testimony and then, second, determine whether the specific scientific principle at issue was “generally accepted” by scientists in that particular field.²⁴ The test was easy for judges to apply, but some felt it was overly broad and excluded valuable scientific testimony.²⁵ As one commentator writing about the genesis of Rule 702, noted:

The *Frye* test was relatively simple, but rigid in its all-or-nothing approach. It was praised as guaranteeing uniformity of decisions, eliminating the need for prolonged admissibility hearings, and providing an effective method to determine the admissibility of the evidence by the specialists. The test was criticized, however, for establishing too large a threshold for useful and otherwise reliable scientific testimony that was novel and not yet ‘generally accepted’ in the field.²⁶

In 1975, Congress approved the Federal Rules of Evidence, a new uniform code that would apply to all federal civil and criminal cases.²⁷ The rules seemingly liberalized the old “general acceptance test” to a less stringent “relevancy standard.”²⁸ The original Rule 702 stated that if “scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue,”²⁹ then a witness

¹⁹ *Id.*

²⁰ See e.g., Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, HARV. L. REV. 40–58 (1901).

²¹ *Frye v. U.S.*, 293 F. 1013 (D.C. Cir. 1923).

²² *Id.* at 1014.

²³ Puzniak, *supra* note 18, at 33.

²⁴ Puzniak, *supra* note 18, at 33.

²⁵ Puzniak, *supra* note 18, at 33.

²⁶ Puzniak, *supra* note 18, at 33.

²⁷ Paul R. Rice & Neals-Erik William Delker, *Federal Rules of Evidence Advisory Committee: A Short History of Too Little Consequence*, 191 F.R.D. 678 (2000).

²⁸ See *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 588 (1993); see also Howard J. Zlotnick & Jr. Lin, *Handwriting Evidence in Federal Courts: From Frye to Kumho*, 13 FORENSIC SCI. REV., 87-99 (2001) [hereinafter Zlotnick & Lin]; but cf. David E. Bernstein, *Frye, Frye, Again: The Past, Present, and Future of the General Acceptance Test*, 41 JURIMETRICS J. 385 (2001) (arguing that *Daubert*, has in fact, evolved into a stricter test than *Frye*).

²⁹ JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN’S FEDERAL EVIDENCE § 702 App.01 (Joseph M. McLaughlin ed., Matthew Bender & Co. 2d ed. 2015).

“qualified as an expert by knowledge, skill, experience, training, or education,” could testify “in the form of opinion or otherwise.”³⁰ However, judges remained uncertain whether the new federal rules overruled the old common law *Frye* standard.³¹ There were also concerns that the rules went too far, that they opened the floodgates for junk science courtroom testimony.³² These concerns came to a head in the 1980s “when some judges grew skeptical of some of the scientific claims in high-profile cases.”³³

The issues were reiterated in the Department of Justice’s Tort Working Group 1986 report examining the underlying causes of the “crisis in insurance availability and affordability.”³⁴ The report decried the “undermining of causation”³⁵ and the “increasingly serious problem in toxic tort cases”³⁶ of faulty science entering into courtroom deliberations. The result was “findings of causation which simply cannot be justified or understood from the standpoint of the current state of credible scientific and medical knowledge” and “a deep and growing cynicism about the ability of tort law to deal with difficult scientific and medical concepts in a principled and rational way.”³⁷

In large part, the root causes of junk science are the economic incentives for both plaintiffs’ attorneys, who will get a lucrative cut from any settlement or win, and expert witnesses who are paid gigantic sums by the hour and who need to find convenient “scientific theories” to bolster their case. As one commentator concluded, “junk science in the courtroom emanates from testimony by expert witnesses hired not for their scientific expertise, but for their willingness, for a price, to say whatever is needed to make the client’s case.”³⁸ Junk science was frequently a scare tactic, employed in settlement negotiations to threaten the other side, with the specter that “so-called ‘expert’ testimony” could be an irreparable blow to the opponent’s case.³⁹

B. Background to current Rule 702

In an effort to address the growing problem, the U.S. Supreme Court clarified Rule 702, the rule governing testimony by expert witnesses under the Federal Rules of Evidence, in its landmark *Daubert* decision.⁴⁰ In *Daubert*, plaintiff-parents sued a pharmaceutical company on behalf of their minor children who were born with serious birth defects.⁴¹ The parents alleged that the mothers’ ingestion of the company’s

³⁰ *Id.*

³¹ Barbara Hughes Erard & Mimi Keidan Seltzer, *Evolving Standard of Scientific Acceptance Under Daubert*, 73 MICH. B.J. 161 (1994).

³² Marc S. Klein, *Expert Testimony in Pharmaceutical Product Liability Actions*, 45 FOOD DRUG COSM. L.J. 393, 394 (1990).

³³ Glaberson, *supra* note 17.

³⁴ U.S. DEP’T OF JUSTICE, REPORT OF THE TORT POLICY WORKING GROUP ON THE CAUSES, EXTENT AND POLICY IMPLICATIONS OF THE CURRENT CRISIS IN INSURANCE AVAILABILITY AND AFFORDABILITY 1-91 (1986), [hereinafter TORT POLICY REPORT].

³⁵ *Id.* at 33.

³⁶ *Id.* at 35.

³⁷ *Id.*

³⁸ Dick Thornburgh, *Junk Science—The Lawyer’s Ethical Responsibilities*, 25 FORDHAM URB. L.J. 449 (1998).

³⁹ *Id.*

⁴⁰ *Daubert, v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

⁴¹ *Id.* at 582.

prescription anti-nausea drug, Bendectin, caused the birth defects.⁴² After reviewing scientific opinions supporting both the plaintiffs' and defendant's position, the district court granted summary judgment to the defendant pharmaceutical manufacturer. The court concluded that the plaintiffs' expert evidence was insufficient to prove that Bendectin caused the birth defects. The court specifically pointed to the plaintiffs' inability to proffer epidemiological evidence from systematic studies of research on people, in support of their claims, and that the plaintiffs' expert testimony, based upon newer laboratory research, including *in vitro* studies, chemical structure analyses and animal studies, was insufficient to prove causation and thus could not be taken to a jury.⁴³ The Ninth Circuit affirmed under the prevailing "general acceptance" standard for scientific evidence, holding that a scientific opinion "is admissible if it is generally accepted as a reliable technique among the scientific community."⁴⁴

On appeal, the U.S. Supreme Court detailed the nature of the scientific opinions that the district court faced.⁴⁵ The defendant's expert witness was a physician and epidemiologist who had "published numerous articles on the magnitude of risk from exposure to various chemical and biological substances."⁴⁶ Summarizing the affidavit of the defendant's expert, which was submitted in support of its motion for summary judgment, the Court stated:

[H]e had reviewed all the literature on Bendectin and human birth defects—more than 30 published studies involving over 130,000 patients. No study had found Bendectin to be a human teratogen (*i.e.*, a substance capable of causing malformations in fetuses). On the basis of this review, Doctor Lamm concluded that maternal use of Bendectin during the first trimester of pregnancy has not been shown to be a risk factor for human birth defects.⁴⁷

The plaintiffs responded to the defendant's motion with the "testimony of eight experts of their own, each of whom had impressive credentials."⁴⁸ Contrary to the defendant expert's affidavit, the plaintiffs' experts asserted that Bendectin could have caused the birth defects.⁴⁹ The plaintiffs' experts based their conclusions on 'in vitro' (test tube) and 'in vivo' (live) animal studies that found a link between Bendectin and malformations; pharmacological studies of the chemical structure of Bendectin that purported to show similarities between the structure of the drug and that of other substances known to cause birth defects; and the 'reanalysis' of previously published epidemiological human statistical studies.⁵⁰

⁴² *Id.*

⁴³ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989), *aff'd*, 95 F.2d 1128 (9th Cir. 1991).

⁴⁴ *Id.*

⁴⁵ *Daubert*, 509 U.S. at 583.

⁴⁶ *Id.* at 582 n.1 (explaining the district court case in *Daubert*).

⁴⁷ *Id.* at 582.

⁴⁸ *Id.* at 583.

⁴⁹ *Id.*

⁵⁰ *Id.*

In deciding the case, the Supreme Court rejected the general acceptance standard as the exclusive basis for assessing the admissibility of expert testimony.⁵¹ Instead, the court held that under the Federal Rules of Evidence, the “basic standard of relevance was a liberal one,” more so than the common law *Frye* test.⁵² With specific regard to Rule 702, “the drafting history makes no mention of *Frye*, and a rigid ‘general acceptance’ requirement would be at odds with the ‘liberal thrust of the Federal Rules and their ‘general approach of relaxing the traditional barriers to ‘opinion’ testimony.’”⁵³ The Court, however, cautioned that simply because the Federal Rules superseded *Frye* did not mean that Rules placed “no limits on the admissibility of purportedly scientific evidence.”⁵⁴

The *Daubert* Court went on to articulate a set of factors that were meant to be non-exclusive guidelines to help judges determine what is valid science, including 1) whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community.⁵⁵ The Supreme Court cautioned that a judge should not vet an expert's testimony based “on the conclusions they generate,” but rather the “focus, of course, must be solely on principles and methodology.”⁵⁶

The Supreme Court concluded that the trial judge was responsible for ensuring that “any and all scientific testimony or evidence admitted is not only relevant but reliable.”⁵⁷ Essentially, *Daubert* deemed trial judges to be “gatekeepers” of scientific evidence, who have the obligation to exclude “unreliable testimony.”⁵⁸

On remand from the Supreme Court, the Ninth Circuit sustained the district court's exclusion of testimony from the plaintiffs' experts under the newly announced *Daubert* standard.⁵⁹ The plaintiffs' experts had not based their testimony on preexisting or independent research, did not publish their work in scientific journals, and did not adequately explain their methodology.⁶⁰ As a result, the testimony of the plaintiffs' experts was inadmissible, and the plaintiffs could not prove causation.⁶¹

⁵¹ *Id.* at 588.

⁵² *Id.* at 587.

⁵³ *Id.* at 588.

⁵⁴ *Id.* at 589.

⁵⁵ *Id.*

⁵⁶ *Id.* at 595.

⁵⁷ *Id.*

⁵⁸ FED. R. EVID. 702 advisory committee's note (2000 amendments).

⁵⁹ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F. 3d 1311 (9th Cir. 1995).

⁶⁰ *Id.* at 1317–19.

⁶¹ *Id.* at 1322.

C. *The role of judge as “gatekeeper” and standards for admissibility of scientific opinion under Rule 702*

Following *Daubert*, Rule 702 was amended in 2000.⁶² The Advisory Committee took pains to emphasize that the *Daubert* factors were meant to guide how courts would evaluate the reliability of scientific testimony—and thus its admissibility—although the factors were by no means an exclusive checklist.⁶³ And, in fact, subsequent to the Supreme Court’s decision, courts have developed additional factors, for example, whether experts are “proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for the purposes of testifying.”⁶⁴

Even when courts rule on preliminary injunctions—which typically proceed faster than proceedings on the merits—a Rule 702 analysis is required. For example, the 10th Circuit held in *Oklahoma v. Tyson Foods*⁶⁵ that a district court did not abuse its discretion in denying a preliminary injunction after finding that expert testimony was unreliable⁶⁶ and entitled to “scant weight”⁶⁷ in accordance with *Daubert*. The State alleged a causal link between poultry litter from poultry farmers and fecal bacteria contamination found in the Illinois River Watershed, but the trial court held that the State could not “demonstrate its likelihood of success on the merits, the first factor required for preliminary injunctive relief” on the causation question.⁶⁸ The trial judge honed in on the fact that the State’s expert testimony had not been peer reviewed or published, and that no one outside the lawsuit had validated the expert’s work.⁶⁹ In denying the preliminary injunction, the court held that even when the judge sits as fact-finder, Rule 702 standards must still be met.

II. THE DISPUTE IN HOBBY LOBBY, AND THE SCIENTIFIC VIEWS THAT WERE THE BASIS FOR THE DECISION

In 1993, Congress passed the Religious Freedom Restoration Act (RFRA), requiring strict scrutiny when a neutral law of general applicability “substantially burden[s] a person’s exercise of religion.”⁷⁰ RFRA was amended in 2000 by the Religious Land Use and Institutionalized Persons Act (RLUIPA), to define “exercise of

⁶² See FED. R. EVID. 702.

⁶³ FED. R. EVID. 702, *supra* note 58.

⁶⁴ See *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1317 (9th Cir. 1995); see *supra* note 58, for a list of various additional factors that have been developed by other courts.

⁶⁵ *Oklahoma v. Tyson Foods*, 565 F.3d 769 (10th Cir. 2009) (holding that the state was unlikely to establish at trial that land application of poultry waste might present an imminent and substantial danger to health or the environment, as required for relief under Resource Conservation and Recovery Act (RCRA) and also that the trial court did not abuse its discretion in denying the preliminary injunction based on a conclusion that the state’s witness testimony was unreliable and entitled to little weight).

⁶⁶ *Id.* at 780.

⁶⁷ *Id.* at 781.

⁶⁸ *Id.* at 775.

⁶⁹ *Id.* at 780.

⁷⁰ *Hobby Lobby*, 134 U.S. at 2754; see also 42 U.S.C. §2000bb (2012).

religion” broadly as any exercise of religion, “whether or not compelled by, or central to, a system of religious belief,”⁷¹ which is to be “construed in favor of a broad protection of religious exercise, to the maximum extent permitted by the terms of this chapter and the Constitution.”⁷²

The *Hobby Lobby* plaintiffs claimed that the 2010 Patient Protection and Affordable Care Act (the Act),⁷³ a federal law that aimed to overhaul the United States insurance system, violated their religious freedom rights under RFRA.⁷⁴ While lawmakers who passed the Act felt it would reform the healthcare system and give uninsured Americans access to affordable and quality healthcare,⁷⁵ the law for a number of reasons caused a political uproar.⁷⁶ Many Republicans alleged that the Act, dubbed “Obamacare,” was a socialized healthcare program that would lead to reductions in quality of care and impose penalties on small businesses.⁷⁷ Republicans in the House have voted more than 50 times to repeal the law.⁷⁸ Some commentators view the Hobby Lobby litigation as politically motivated, just one of many lawsuits brought by ideologically driven plaintiffs who are part of a broader effort to repeal the controversial Act.⁷⁹

One of the key provisions in the Act is Section 2713, which prohibits group health insurance plans from imposing cost-sharing requirements, such as deductibles or copayments, for a number of “preventive health services” including “preventive care and screenings” for women.⁸⁰ Congress did not define “preventive care” in the Act but left it up to the Health Resources and Services Administration (HRSA) to determine what it would encompass.⁸¹

⁷¹ 42 U.S.C. § 2000cc-5(7)(A) (2015). In 2006, the Supreme Court upheld the Constitutionality of the Religious Freedom Restoration Act in *Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal et al.*, 125 S. Ct. 1846 (2006).

⁷² 42 U.S.C. § 2000cc-3 (2012).

⁷³ 42 U.S.C. § 300gg-13 (2012).

⁷⁴ *Hobby Lobby*, 134 S. Ct. at 2759. Hobby Lobby Stores, Inc. is a nationwide chain of arts and crafts stores owned by Christians; Conestoga Wood Specialties is a manufacturing company owned by Mennonites. *Id.* at 2764, 2765.

⁷⁵ Patient Protection and Affordable Care Act, Pub. L. 111-148, §5000, 124 Stat. 588, 120-1020 (2010).

⁷⁶ Susan Cornwell, *Republicans Vow to Keep Fighting Obamacare, Despite Court Ruling*, REUTERS, June 25, 2015, <http://news.yahoo.com/republicans-vow-keep-fighting-obamacare-despite-court-ruling-160811704.html>.

⁷⁷ *Id.*; see also James Surowiecki, *The Business End of Obamacare*, THE NEW YORKER, OCT. 14, 2013, <http://www.newyorker.com/magazine/2013/10/14/the-business-end-of-obamacare>.

⁷⁸ Kathleen Miller & Terrence Dopp, *Core of Obamacare Would Be Repealed in Bill Passed by U.S. House*, BLOOMBERG POLITICS, Oct. 23, 2015, <http://www.bloomberg.com/politics/articles/2015-10-23/core-of-obamacare-would-be-repealed-in-bill-passed-by-u-s-house>.

⁷⁹ See Stephanie Mencimer, *Are You There God? Its Me, Hobby Lobby*, MOTHER JONES, Mar. 21, 2014, <http://www.motherjones.com/politics/2014/03/hobby-lobby-supreme-court-obamacare>; See also Sam Baker, *Is SCOTUS Already Expanding on the Hobby Lobby Ruling?*, THE ATLANTIC, July 7, 2014, <http://www.theatlantic.com/politics/archive/2014/07/is-scotus-already-expanding-on-the-hobby-lobby-ruling/440931/>; Dan Diamond, *Hobby Lobby Isn't the End: Four Other Anti-ACA Lawsuits to Watch*, ADVISORY BOARD: DAILY BRIEFING BLOG (June 25, 2014), <http://www.advisory.com/daily-briefing/blog/2014/06/hobby-lobby-isnt-the-end-other-anti-obamacare-lawsuits-still-loom>.

⁸⁰ 42 U.S.C. § 300gg-13 (2015).

⁸¹ *Id.*

HRSA adopted the evidence-based recommendations of the Institute of Medicine, an independent non-profit dedicated to health policy and research that is essentially the “health arm” of the National Academy of Sciences.⁸² The Institute recommended coverage of eight preventive services, including all FDA-approved methods of contraception,⁸³ without cost sharing.

The *Hobby Lobby* plaintiffs objected to their corporations providing health insurance coverage to female employees for four specific contraceptives, which they believed were abortifacients.⁸⁴ The plaintiffs held the religious belief that life begins at fertilization,⁸⁵ and that any contraceptive method that disrupts the fertilized egg is an abortifacient.⁸⁶ The Supreme Court summarized the plaintiffs’ position as objecting to any contraceptive that prevents “an already fertilized egg from developing any further by inhibiting its attachment to the uterus.”⁸⁷ Though not objecting to coverage for all contraceptives,⁸⁸ the *Hobby Lobby* plaintiffs complained about these four: *Ella* (ulipristal

⁸² DIPTI SINGH, NATIONAL HEALTH LAW PROGRAM, SUMMARY OF THE SUPREME COURT’S DECISION ON THE ACA’S CONTRACEPTIVE COVERAGE REQUIREMENT, (July 7, 2014), <http://www.healthlaw.org/publications/browse-all-publications/Hobby-lobby-analysis#>.

⁸³ *Id.* A contraceptive is “an agent to prevent conception.” STEDMAN’S MEDICAL DICTIONARY, available online at WestlawNext (database updated November 2014).

⁸⁴ *Hobby Lobby*, 134 U.S. at 2759. The Court did not define the terms “abortifacient” or “abortion.” According to Stedman’s Medical Dictionary abortifacient is defined as “1. Producing abortion 2. An agent that produces abortion.” STEDMAN’S *supra* note 83. Stedman’s Medical Dictionary defines abortion as “1. Expulsion from the uterus of an embryo or fetus before viability (20 weeks' gestation [18 weeks after fertilization] or fetal weight less than 500 g). A distinction made between abortion and premature birth is that premature infants are those born after the stage of viability but before 37 weeks' gestation. Abortion may be either spontaneous (occurring from natural causes) or induced (artificially or therapeutically). 2. The arrest of any action or process before its normal completion.” *Id.* Underlying the scientific and “values” debates about contraception, contraceptives and abortion are often conflicting definitions for the core terms.

⁸⁵ *Hobby Lobby* 2764–66. Stedman’s Medical Dictionary defines fertilization as, “The process beginning with penetration of the secondary oocyte by the sperm and completed by fusion of the male and female pronuclei.” See STEDMAN’S *supra* note 83.

⁸⁶ First Amended Verified Complaint ¶30, *Conestoga Wood Specialities Corp. v. Sebelius*, No. 5:12-CV-06744-MSG (E.D. Pa. Jan. 11, 2013) (“The Mennonite Church teaches that taking life which includes anything that terminates a fertilized embryo is intrinsic evil and a sin against God to which they are held accountable. Therefore, abortion and any abortifacient contraception that may cause an abortion is equally objectionable to the Plaintiff”); Verified Complaint at ¶7, *Hobby Lobby v. Sebelius*, 870 F.Supp.2d 1278 (W.D. Okla. 2012) (No. CIV-12-1000-HE) (“The Green family’s religious beliefs forbid them from participating in, providing access to, paying for, training others to engage in, or otherwise supporting abortion-causing drugs and devices”). Note that the plaintiffs “have no religious objection to providing coverage for non-abortion causing contraceptive drugs and devices.” *Id.* at ¶57.

⁸⁷ *Hobby Lobby*, 134 S. Ct. at 2754. The Court also noted that federal regulations define pregnancy as beginning at implantation, citing 62 Fed. Reg. 8611 (1997); 45 CFR §46.202(f) (2013). *Id.* at n.7. The technical terms for attachment to the uterus is “implantation”, as defined in Stedman’s Medical Dictionary “1. Attachment of the blastocyst to the endometrium, and its subsequent embedding in the compact layer, occurring 6–7 days after fertilization of the oocyte in humans.” STEDMAN’S *supra* note 83.

⁸⁸ The plaintiff’s views were markedly different from the views of traditional Catholics, represented by the United States Conference of Catholic Bishops (USCCB), which held an even more stringent view and lobbied adamantly against the *entire* slate of 20 contraceptives. The USCCB noted in its campaign against the mandate that contraception “should not be considered part of preventive healthcare because pregnancy is not a disease.” See *Love and Sexuality*, U.S. CONF. CATH. BISHOPS, <http://www.usccb.org/beliefs-and-teachings/what-we-believe/love-and-sexuality/index.cfm#contraception> (Last visited Jan. 1, 2016). The

acetate), *Plan B* (levonorgestrel), and two types of intrauterine devices (IUDs): *ParaGard* (or copper IUDs) and *Mirena* and *Skyla* (or levonorgestrel-releasing IUDs).⁸⁹

III. THE JUDICIAL TREATMENT OF THE SCIENTIFIC VIEWS OFFERED BY THE *HOBBY LOBBY* PLAINTIFFS: NO RULE 702 REVIEW BY ANY COURT

Despite the mandate of Rule 702, there was no Rule 702 review by any federal court in the *Hobby Lobby* litigation. There was only an indirect reference made to the fact that the plaintiff proffered no evidence showing that the four contraceptives in question were abortifacients in a dissenting opinion by 10th Circuit Judge Mary Beck Briscoe.⁹⁰ Judge Briscoe opined that the plaintiffs did not meet their evidentiary burden to show as a scientific matter that these contraceptives were abortifacients.⁹¹ Without mentioning Rule 702, the dissent was clearly troubled by the absence of valid scientific evidence.

Specifically, Judge Briscoe noted that “there is no evidentiary support in the record for plaintiffs’ allegations that the objected-to contraceptive drugs and devices actually have the potential to prevent implantation of fertilized eggs.”⁹² While there was “agreement among the parties and amici that intrauterine devices have such potential,” by contrast, she noted, “the same cannot be said about the challenged contraceptive drugs (e.g., Plan B and Ella).”⁹³ She concluded: “In light of these evidentiary deficiencies, I fail to see how plaintiffs could reasonably be said to have carried their burden of establishing their entitlement to a preliminary injunction.”⁹⁴

IV. SCIENTIFIC OPINIONS ABOUT WHETHER THE FOUR *HOBBY LOBBY* METHODS ARE ABORTIFACIENTS

The *Hobby Lobby* plaintiffs took the position that life begins at fertilization,⁹⁵ and that the four methods of contraception, which they objected to, prevent implantation of a fertilized egg.⁹⁶ In this section, I first look at scientific opinions on reproduction, specifically opinions about the process of ovulation, how an egg gets fertilized, how implantation occurs, and at what stage in the reproductive process scientists define the beginning of pregnancy. I then review each of the four *Hobby Lobby* contraceptives in

USCCB, joined forces with the *Hobby Lobby* plaintiffs in opposing the mandate, *see, e.g.*, Brief of the United States Conference of Catholic Bishops as Amicus Curiae in Support of Hobby Lobby and Conestoga Wood Specialties Corp., et al., *Sebelius v. Hobby Lobby Stores, Inc.*, No. 13-354 (Jan. 28, 2014), <http://www.usccb.org/about/general-counsel/amicus-briefs/upload/amicus-13-354-13-356-sebelius-hobby-lobby-conestoga-wood.pdf>.

⁸⁹ *Hobby Lobby*, 134 S. Ct. at 2762–63, n.6; *see also* Brief for Petitioners at 10 n.4, *Sebelius v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014) (No. 13-354).

⁹⁰ *Hobby Lobby v. Sebelius*, 723 F.3d 1114, 1164–65 (10th Cir. 2013) (Briscoe, J., dissenting).

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Hobby Lobby*, 134 S. Ct. at 2764–66.

⁹⁶ *Id.*

terms of their mechanism of action—specifically, scientific opinions about (1) how the contraceptive works, and (2) whether the contraceptive acts on the process of ovulation, acts before or after fertilization, or acts by interfering with implantation of the blastocyst in the endometrial lining of the uterus.

A. *The Reproductive Process, Pregnancy, and Contraception*

The first step in the reproductive process is ovulation. Each month inside a woman's ovaries, eggs grow in small, fluid-filled sacs called follicles.⁹⁷ During ovulation, one of the eggs erupts from the follicle, typically about two weeks before a woman starts menstruation.⁹⁸ After the egg exits the follicle, the follicle develops into something called the corpus luteum.⁹⁹ The corpus luteum releases a hormone that thickens the lining of the uterus, "getting it ready for the egg."¹⁰⁰ Essentially, in order for the egg to be fertilized by the sperm, the follicles must burst open in order for the eggs to travel to the fallopian tube.¹⁰¹

Normally, only one egg is released at one time, but occasionally two or more erupt during the menstrual cycle.¹⁰² Typically, an egg erupts from a woman's ovary on the 14th to 16th day of the approximately 28-day menstrual cycle.¹⁰³ "At ovulation, the mucus in the cervix becomes more fluid and more elastic, allowing the sperm to enter the uterus rapidly."¹⁰⁴ The sperm, upon entering the vagina, move through the cervix into the uterus and toward the "funnel-shaped end of the fallopian tube—the usual site of fertilization."¹⁰⁵ When a sperm penetrates the egg, fertilization results.¹⁰⁶

The next step is that the fertilized egg (zygote) "divides repeatedly as it moves down the fallopian tube to the uterus. First, the zygote becomes a solid ball of cells. Then it becomes a hollow ball of cells called a blastocyst. Inside the uterus, the blastocyst implants in the wall of the uterus, where it develops an embryo attached to a placenta and surrounded by fluid-filled membranes."¹⁰⁷

There is a general consensus in the medical community that pregnancy begins upon implantation of the blastocyst in the uterine wall. As a group of 15 doctors, scientists, and medical professional associations wrote in a brief to the Supreme Court, "[p]regnancy is established only upon the conclusion of such implantation."¹⁰⁸ This definition follows the American College of Obstetricians and Gynecologists' definition: the term "pregnancy" refers to the period between the implantation of the embryo in the

⁹⁷ THE MERCK MANUAL OF MEDICAL INFORMATION 1435–37 (Mark Beers ed., Simon & Shuster 2nd Home ed. 2003).

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Brief of Physicians For Reproductive Health, et al., as Amici Curiae Supporting Petitioners at 12, *Sebelius v. Hobby Lobby Stores, Inc.*, 134 S. Ct 2751 (2013) (No. 13-354).

uterus and childbirth.¹⁰⁹

There is a clear scientific distinction between contraceptives and abortifacients. “[A] ‘contraceptive’ refers to that which prevents fertilization of an egg or prevents implantation of a fertilized egg—in other words, it prevents a pregnancy from taking place.”¹¹⁰ On the other hand, an abortifacient “works to disturb an embryo already implanted in the uterine lining, which necessarily occurs after a pregnancy has been established.”¹¹¹

While there is a consensus view for how the four *Hobby Lobby* contraceptives likely act to block reproduction, researchers have had some difficulty, depending on the particular contraceptive at issue, in fully explaining the occasional pregnancy.¹¹² Research knowledge is constrained by a several factors such as the inability of scientists to identify the exact moment of fertilization of the egg and the difficulty of finding research subjects (not many women of child-bearing age are willing to have their reproductive systems flushed in order to be studied).¹¹³ There are also ethical considerations because, in certain cases, testing would involve a human embryo.¹¹⁴

Another factor adding to the difficulty of determining how a particular contraceptive works is the general instability in the process of fertilization and implantation. Loss of fertilized eggs is actually the norm. In healthy women not practicing any method of contraception, an estimated 70 percent of fertilized eggs are lost before or at the time of implantation¹¹⁵.

B. *Ella*

Ella is a pill that contains 30 mg of ulipristal acetate (UPA). Its product label recommends use within 120 hours of unprotected sex.¹¹⁶ The strong scientific consensus is that *Ella* works by inhibiting ovulation,¹¹⁷ and that *Ella*'s main component, ulipristal acetate, can prevent ovulation and even delay ovulation on the day of the LH peak for twenty-four to forty-eight hours after the pill is taken.¹¹⁸

¹⁰⁹ Maurizio Guida, et al., *Emergency Contraception: An Updated Review*, 1 TRANSLATIONAL MED. @ UNISA 271, 273 (2011).

¹¹⁰ Brief of Physicians For Reproductive Health, *supra* note 108, at 13.

¹¹¹ *Id.*

¹¹² E.g., Maria Elena Ortiz & Horacio B. Croxatto, *Copper-T Intrauterine Device and Levonorgestrel Intrauterine System: Biological Bases of Their Mechanism of Action*, 75 CONTRACEPTION S16, S18 (2007) (discussing in Table 3 that the number of control women was 111 and women with IUDs was even lower at 56 in the studies looking at the recovery of ova. This is just one example of the very few number of events that have been directly studied in human females).

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ See CAROL COUGHLIN, ET AL. *Recurrent Implantation Failure: Definition and Management* 28 REPRODUCTIVE BIOMEDICINE ONLINE 14, 15 (2014) (stating that because the probability for an embryo to successfully implant is only approximately 30%, the probability of it failing to implant is approximately 70%).

¹¹⁶ Association of Reproductive Health Professionals, *The Facts About Emergency Contraception*, (Dec. 2011), <http://www.arhp.org/publications-and-resources/clinical-fact-sheets/facts-about-ec>.

¹¹⁷ Ortiz, *supra* note 112.

¹¹⁸ Kristina Gemzell Danielsson, Cecilia Berger & P.G.L. Lalitkumar, *Emergency Contraception—Mechanisms of Action*, 87 CONTRACEPTION 300, 302 (2013) (“...prior to the LH rise, UPA inhibited 100

There is a minority view that Ella works by impacting endometrial development.¹¹⁹ Endometrial tissue affects whether an egg can properly implant.¹²⁰ On that basis, an argument is sometimes raised that Ella may affect post-fertilization implantation.¹²¹ However, when used at the recommended dose and timing for emergency contraception, no effect on the endometrium has been seen.¹²²

C. Plan B (Levonorgestrel or “LNG ECP”)

Levonorgestrel is the scientific name for the pill called “Plan B” and other hormonal pills that contain 1.5 mg LNG. It is a “synthetic version of the naturally-occurring hormone progesterone.”¹²³ Plan B works by inhibiting ovulation.¹²⁴ The U.S. Food and Drug Administration (FDA) approved Plan B packaging with a statement that a post-fertilization effect is possible.¹²⁵ A reporter for the New York Times investigating the issue of potentially-faulty FDA labeling of emergency contraceptives, such as Plan B, said that the newspaper had reviewed “hundreds of pages of approval process documents” but “found no discussion of evidence supporting implantation effects.”¹²⁶

Plan B’s maker—Barr Pharmaceuticals, later acquired by Teva Pharmaceuticals—asked the FDA not to list an implantation effect on the label.¹²⁷ While the FDA declined to comment as to why the company’s request had been denied,¹²⁸ at least some experts

percent of follicular ruptures...when the size of the leading follicle was ≥ 18 mm, follicular rupture failed to occur within 5-6 days following treatment from 44 percent to 56 percent. Even on the day of the LH peak, UPA could delay ovulation from 24-48 hrs...”). See also Kate McKeage & James D. Croxtall, *Ulipristal Acetate: A Review of Its Use in Emergency Contraception*, 71 DRUGS 935, 935-36 (2011) (“The principal effect of ulipristal acetate is to inhibit or delay ovulation. This effect may result from the drug’s ability to delay the onset of luteinizing hormone (LH) surge or postpone LH peak if LH surge has started, or possibly by a direct inhibitory effect on follicular rupture, when administered in the follicular phase (including just before ovulation).”). See also Kristina Gemzell-Danielsson, *Mechanism of Action of Emergency Contraception*, 82 CONTRACEPTION 404, 404-409 (2010).

¹¹⁹ Bruno Mozzanega, MD, et al., *Ulipristal Acetate: Critical Review About Endometrial and Ovulatory Effects in Emergency Contraception*, 21 REPRODUCTIVE SCIENCES 678, 678-79, (2014).

¹²⁰ *Id.*

¹²¹ The *Hobby Lobby* plaintiffs complained that Ella and Plan B worked similarly to the abortion drug RU 486 or Mifepristone. See Verified Complaint ¶¶54-55, *Hobby Lobby v. Sebelius*, No. CIV-12-1000-HE (W.D. Okla. Sept. 12, 2012) (Trial Pleading); See also First Amended Verified Complaint ¶46, *Conestoga Wood Specialties Corp. v. Sebelius*, No. 5:12-CV-06744-MSG (E.D. Pa. Jan. 11, 2013) (Trial Pleading). However, unlike ELLA Ella and Plan B, mifepristone acts on eggs already implanted in the uterus by affecting progesterone activity and causing uterine contractions. See Label for mifepristone posted on U.S. Food and Drug Administration website, http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/020687s010-lbl.pdf.

¹²² Gemzell-Danielsson, *supra* note 118, at 304.

¹²³ Brief of Physicians For Reproductive Health, *supra* note 108, at 8.

¹²⁴ International Federation of Gynecology & Obstetrics (FIGO), *Statement on Mechanisms of Action for Emergency Contraception* (Mar. 2011),

http://www.figo.org/sites/default/files/uploads/MOA_FINAL_2011_ENG.pdf

¹²⁵ Pam Belluck, *Abortion Qualms on Morning-After Pill May Be Unfounded*, N.Y. TIMES, June 6, 2012, at A1.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

hold the view that the FDA required an implantation mechanism on the label because of endometrial effects, even though such effects do not interfere with implantation:

[D]aily birth control pills, some of which contain Plan B's active ingredient, appear to alter the endometrium, the lining of the uterus into which fertilized eggs implant. Altering the endometrium has not been proven to interfere with implantation . . . scientists say that unlike the accumulating doses of daily birth control pills, the one-shot dose in morning-after pills does not have time to affect the uterine lining.¹²⁹

The most up-to-date scientific consensus suggests that there is no meaningful scientific evidence proving that Plan B interferes with the implantation of a fertilized egg. In March 2011, the International Federation of Gynecology and Obstetrics (FIGO) published a joint statement that levonorgestrel-only emergency contraceptive pills (LNG ECPs) work by impairing ovulation, and do not inhibit implantation.¹³⁰ The statement summarized key findings from numerous scientific studies about levonorgestrel's effects on ovulation, sperm, implantation of the blastocyst and pregnancy:

- **Ovulation:** The FIGO statement cited eight studies that showed “strong direct evidence that LNG ECPs prevent or delay ovulation.¹³¹ This is the primary mechanism of action for LNG ECPs.”¹³²
- **Implantation:** The FIGO statement cited a variety of studies to rebut the contention that LNG ECPs affect implantation:¹³³
 - Two studies that confirmed a woman's cycle day via “hormonal analysis” compared to other studies, which “used a women's self-reported day.”¹³⁴ “In these studies no pregnancies occurred in women who took ECPs before ovulation; while pregnancies occurred only in women who took ECPs on or after the day of ovulation, providing evidence that ECPs were unable to prevent implantation.”¹³⁵
 - A number of studies “have evaluated whether ECPs produce changes in the histological and bio-chemical characteristics of the endometrium. Most studies show that LNG ECPs have no such effect on the endometrium, indicating that they have no mechanism to prevent implantation. One of these studies found that following administration of double the standard dose of LNG, there are only minor or no alterations in endometrial receptivity. One study found a single altered endometrial parameter only when LNG was administered prior to the LH surge, at a time when ECPs inhibit ovulation.”¹³⁶ In this latter study, endometrial

¹²⁹ *Id.*

¹³⁰ International Federation of Gynecology & Obstetrics, *supra* note 124. The FIGO statement cites to 17 studies published in scientific journals to support this conclusion.

¹³¹ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹³² International Federation of Gynecology & Obstetrics, *supra* note 124.

¹³³ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹³⁴ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹³⁵ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹³⁶ International Federation of Gynecology & Obstetrics, *supra* note 124.

function being altered made no difference if the drug inhibited ovulation altogether, because fertilization of an egg cannot take place without ovulation.¹³⁷

- One study that showed LNG emergency contraceptive pills “did not prevent the attachment of human embryos to a simulated (in vitro) endometrial environment.”¹³⁸
- Two studies involving animals “demonstrated that LNG ECPs did not prevent implantation of the fertilized egg in the endometrium.”¹³⁹
- **Sperm:** The FIGO statement noted that “contradictory results exist regarding whether LNG taken post-coitally and in doses used for ec (emergency contraception) affects sperm function.”¹⁴⁰ The FIGO statement, citing two studies, said “early studies suggested that LNG ECPs interfere with sperm motility by thickening cervical mucus.”¹⁴¹ The statement cautioned, however, that “two in vitro studies found that LNG in doses used for ec has no direct effect on sperm function. Recent in vivo studies found no effect of LNG on the number of viable sperm found in the female genital tract 24-28 hours after taking LNG. Interference in sperm migration is also a possible explanation in women who took LNG ECP before ovulation, but had documented follicle rupture in the following 5 days, yet did not get pregnant.”¹⁴² The FIGO statement concluded, “[g]iven these results, this mechanism of action is still uncertain and warrants further studies.”¹⁴³
- **Effect on Pregnancy:** The FIGO Statement concluded that LNG taken as an emergency contraceptive has no apparent effect on pregnancy: “Two studies of women who became pregnant in cycles when they took LNG ECPs found no difference between pregnancy outcomes of women who had taken LNG ECPs and those who had not. Variables included miscarriage, birth weight, malformations, and sex ratio, indicating that LNG ECPs have no effect on an established pregnancy even at very early stages.”¹⁴⁴

Based on 24 referenced studies, FIGO reached the conclusion that “inhibition or delay of ovulation is LNG ECP’s principal and possibly only mechanism of action.”¹⁴⁵ Further:

Review of the evidence suggests that LNG ECPs cannot prevent implantation of a fertilized egg. Language on implantation should not be included in LNG ecP product labeling. The fact that LNG ECPs have no demonstrated effect on implantation explains why they are not 100% effective in preventing pregnancy, and are less effective the later they are

¹³⁷ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹³⁸ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹³⁹ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁴⁰ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁴¹ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁴² International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁴³ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁴⁴ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁴⁵ International Federation of Gynecology & Obstetrics, *supra* note 124.

taken. Women should be given a clear message that LNG ECPs are more effective the sooner they are taken. LNG ECPs do not interrupt a pregnancy (by any definition of the beginning of pregnancy). However, LNG ECPs can prevent abortions by reducing unwanted pregnancy.¹⁴⁶

D. Intrauterine devices (IUD): copper-releasing IUD and levonorgestrel-releasing IUD

Two of the four contraceptives at issue in *Hobby Lobby* are IUDs, one of which releases copper and the other releases the hormone levonorgestrel.¹⁴⁷ A number of studies suggest that the mechanism of IUD effectiveness typically occurs before implantation: “The common belief that the usual mechanism of action of IUDs in women is destruction of embryos in the uterus is not supported by empirical evidence.”¹⁴⁸ The usual mechanism of action in IUDs is by preventing fertilization (“preventing the encounter of healthy gametes and the formation of viable embryos”).¹⁴⁹ Even if sperm do reach the site of fertilization, there is evidence to suggest that they do not fertilize the egg because of endometrial glycodelin secretion, which are substances secreted into the female reproductive tract by the endometrium.¹⁵⁰ On the other hand, there have been instances of fertilized eggs, and while interference with a fertilized egg may be “exceptional” in the presence of a copper or hormonal IUD, it can occur, even if rarely.¹⁵¹ Overall, the bulk of research supports the conclusion that IUDs do not interfere with the reproductive process after fertilization has taken place.¹⁵² Nonetheless, there is not full consensus that IUDs prevent pregnancy by acting only before fertilization.¹⁵³

1. ParaGard (copper-releasing IUD)

The consensus on the copper-releasing IUD is that it works as a contraceptive by preventing the sperm from reaching the fallopian tube to fertilize the ovum.¹⁵⁴ Copper ions in ParaGard “stimulate an intrauterine inflammatory reaction that is cytotoxic to the

¹⁴⁶ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁴⁷ See Description of Terms, The Henry J. Kaiser Family Foundation, *Intrauterine Devices (IUDs): Access for Women in the U.S.* (July 9, 2015), <http://kff.org/womens-health-policy/fact-sheet/intrauterine-devices-iuds-access-for-women-in-the-u-s/>.

¹⁴⁸ Ortiz, *supra* note 112, at S28.

¹⁴⁹ Ortiz, *supra* note 112, at S28.

¹⁵⁰ Ortiz, *supra* note 112, at S18.

¹⁵¹ Ortiz, *supra* note 112, at S28.

¹⁵² Gemzell-Danielsson, *supra* note 118, at 304. These conclusions refers to chronic use of IUDs, as distinguished from the situation when a copper IUD is used as an emergency contraception, with the expectation that it may prevent implantation due to copper's effect of altering molecules present in the endometrial lining of the uterus.

¹⁵³ See, e.g., Joseph B. Stanford & Rafael T. Mikolajczyk, *Mechanisms of Action of Intrauterine Devices: Update and Estimation of Postfertilization Effects*, 187 AM. J. OBSTET. GYNECOL. 1699, 1699 (2002).

¹⁵⁴ Anita Nelson, *Safety, Efficacy and Patient Acceptability of the Copper T-380A Intrauterine Contraceptive Device*, 4 CLINICAL MED. INSIGHTS: WOMEN'S HEALTH 35, 35 (2011).

sperm and phagocytizes [destroys] them; no viable spermatozoa remain in the endometrial cavity 18 hours after natural insemination.”¹⁵⁵

In short, copper is toxic to sperm and kills them before they reach the egg.¹⁵⁶ As one study concluded about copper IUDs: “there is *no* evidence that the IUD works after implantation.”¹⁵⁷ Further, “the evidence that IUDs do not work after fertilization by blocking implantation comes from several different experimental designs.”¹⁵⁸ There are several indications from scientific studies that copper IUDs work before fertilization takes place:

- “By studying ova retrieved during sterilization procedures from women who had mid cycle coitus, it was seen that none of the specimens from women using IUDs displayed normal cellular division indicating successful fertilization. However, 50 percent of the ova from the women who used no method showed such division.”¹⁵⁹
- “Similarly, no eggs were recovered from the uterine cavities of 56 IUD users within 132 hours after the LH peak compared to 4 eggs found in the 115 control women.”¹⁶⁰
- “In addition, the fact that CuT380A [copper-releasing IUD] dramatically decreases ectopic pregnancy risks supports the fact that the site of action is before the fallopian tube—that fertilization is blocked.”¹⁶¹

Also of note, recent studies “have revealed that the copper IUD decreases endometrial HOXA10 expression, which is essential for endometrial receptivity, but the clinical significance of those changes is not known.”¹⁶² However, this point is moot if there is no fertilization in the first place, and may be irrelevant to any *Hobby Lobby* scientific review.

Finally, there is also an opposing view, albeit based on research almost 20 years old and with a very small set of data , that copper IUDs work both as a pre-fertilization spermicidal action and as a post-fertilization inhibition of uterine implantation.¹⁶³

2. Mirena and Skyla (levonorgestrel-releasing IUD or LNG IUD)

This type of IUD acts by releasing progestin, a synthetic steroid that is different from natural progesterone.¹⁶⁴ These contraceptives interfere with the sperm’s ability to fertilize the egg.¹⁶⁵ The general medical view is that LNG IUDs work with a similar

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ Joseph A. Spinnato II MD, *Mechanism of Action of Intrauterine Contraceptive Devices and Its Relation to Informed Consent*, 176 AM. J. OBSTET. GYNECOL., 503, 503–506 (1997).

¹⁶⁴ *Id.*

¹⁶⁴ Abdelhamid M. Attia, Magdy M. Ibrahim & Ahmed M. Abou-Setta, *Role of the Levonorgestrel Intrauterine System in Effective Contraception 7 Patient Pref. and Adherence 777, 778* (2013).

¹⁶⁵ Ortiz, *supra* note 112, at S18.

mechanism of action as copper-releasing IUDs, that is, they prevent fertilization.¹⁶⁶ However, just as with the copper IUD, there is not full scientific agreement. One review of the scientific literature on the mechanism of action for IUDs noted that in rare instances, LNG-IUDs may interfere with a fertilized egg, as suggested in a study by Alvarez et al., where there was one fertilized egg recovered from a LNG IUD user.¹⁶⁷

V. UNDER RULE 702, WOULD A COURT HAVE ADMITTED EVIDENCE THAT THESE FOUR METHODS ARE ABORTIFACIENTS?

Under the court's gatekeeping function—which applies to all expert testimony¹⁶⁸—the trial judge assesses whether scientific opinions are admissible, using the non-exclusive standards of Rule 702.¹⁶⁹ The inquiry focuses on whether expert opinions are sufficiently reliable to be admitted before any fact-finding takes place (whether the fact-finder is the jury or a judge).¹⁷⁰ The “focus, of course, must be solely on principles and methodology, not on the conclusions they generate.”¹⁷¹

Admissibility is not equivalent to a fact-finding conclusion. Thus, competing opinions can be admitted so long as they meet the Rule 702 requirements.¹⁷² Proponents “do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable. . . . The evidentiary requirement of reliability is lower than the merits standard of correctness.”¹⁷³

There are four components to a Rule 702 analysis, although the components can be overlapping.¹⁷⁴ For purposes of this review, I assume that one or more of the authors from the articles cited in Section IV would testify on whether the four contraceptives are abortifacients. On that basis, I approach the Rule 702 analyses as follows.

First, in Section A below, I discuss admissibility under Rule 702(a) and show that identifying a qualified expert is not likely to be an impediment to admissibility of opinions contesting the *Hobby Lobby* beliefs about the four contraceptives.

Second, in Section B below, I analyze the Rule 702(b), (c) and (d) factors for each contraceptive. The main reason for analyzing those factors together is that in this situation, the Rule 702 factors—testimony based on sufficient facts, the product of reliable principles and methods, and the reliable application of those principles and methods—are highly overlapping. *Hobby Lobby*, unlike *Daubert*, does not involve the application of scientific principles and methods to a single personal injury plaintiff. The

¹⁶⁶ Ortiz, *supra* note 112, at S28.

¹⁶⁷ Ortiz, *supra* note 112, at S27.

¹⁶⁸ Kumho Tire Co. v. Carmichael, 119 S. Ct. 1167, 1178 (1999).

¹⁶⁹ FED. R. EVID. 702.

¹⁷⁰ *Id.*

¹⁷¹ *Daubert*, 509 U.S. at 595.

¹⁷² FED. R. EVID. 702, *supra* note 58.

¹⁷³ In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 744 (3d Cir. 1994). See also *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1318 (9th Cir. 1995) (scientific experts might be permitted to testify if they could show that the methods they used were also employed by “a recognized minority of scientists in their field.”).

¹⁷⁴ FED. R. EVID. 702.

principles and methods shown in the scientific literature are not dependent on a particular individual but rather apply more generally to a widespread group of individuals. Clearly, this was a case where the plaintiffs did not have individualized medical conditions; rather they made general medical and scientific claims in their briefs to the court. Thus, the court, in exercising its gatekeeper function, would evaluate expert testimony as it is applied generally to the claims at hand, rather than to a specific person.

Here, the focus is on the reliability of scientific data and methods for studying the general mechanism of action in a given contraceptive, and whether an expert's opinion shows that she reliably applied scientific principles and methods to her conclusions about the mechanism of action in a particular contraceptive. As has been recognized by others, there is considerable redundancy among those factors, and treating them as completely independent would be pushing distinctions that may not exist.¹⁷⁵

A. *Will The Expert's Specialized Knowledge Help The Trier Of Fact To Determine Whether Each Contraceptive Is An Abortifacient Under Rule 702(A)?*

How each contraceptive works is not a matter of everyday experience or intuition—it is a matter of “scientific, technical, or other specialized knowledge.”¹⁷⁶ The authors of the scientific articles cited in Section IV were qualified by education, training and experience. The authors hold a medical degree and/or a doctoral degree in an appropriate science, and specialize in gynecology and/or reproductive health. If one or more of these scientists were called to testify at trial, their opinions about contraceptives would likely pass muster under Rule 702(a) because each of them has the requisite “scientific, technical, or other specialized knowledge” to help the trier of fact understand a key issue: whether a particular contraceptive is an abortifacient, the “fact in issue.”¹⁷⁷

Even when a witness does not have the strongest of credentials, it would be unusual—indeed, possibly an abuse of the trial court's discretion—for an M.D. practicing or researching in the area of gynecology or obstetrics to be barred from testifying on the basis of lack of specialized knowledge.¹⁷⁸ Disputes over the strength of qualifications and credentials usually go to the weight that a fact-finder gives the expert testimony, rather than to the admissibility of the testimony.¹⁷⁹ As the *Daubert* Court noted, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”¹⁸⁰

¹⁷⁵ See, e.g., Munia Jabbar, *Overcoming Daubert's Shortcomings in Criminal Trials: Making the Error Rate the Primary Factor in Daubert's Validity Inquiry*, 85 NYU LAW REV. 2034–64 (2010); DAVID L. FAIGMAN, ET AL., 1 MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY 20 (2d ed. 2002).

¹⁷⁶ FED. R. EVID. 702.

¹⁷⁷ FED. F. EVID. 702(a).

¹⁷⁸ Weinstein, *supra* note 29 at § 702.04(1)(a).

¹⁷⁹ See, e.g., *Jahn v. Equine Services, PSC*, 233 F.3d 382, 393 n.8 (6th Cir. 2000); *Arkansas Game and Fish Comm'n v. United States*, 736 F.3d 1364, 1378 (Fed. Cir. 2013).

¹⁸⁰ *Daubert*, 509 U.S. at 596.

In short, Rule 702(a) would not be an impediment to offering the scientific opinions discussed in Section IV because those rendering the opinions have the required specialized knowledge.

B. Would the Court Have Admitted Evidence that Ella Is or Is Not an Abortifacient?

The overwhelming view from medical literature and numerous peer-reviewed scientific studies is that Ella works by inhibiting ovulation—a process that takes place before fertilization and before implantation of a fertilized egg. That conclusion hinges on scientific facts and data subjected to peer review. Moreover, as shown in Section IV, there is virtually no reliable basis for disputing that this opinion is the product of reliable scientific principles and methods, which were reliably applied to the research. A court should easily admit those opinions about Ella under Rule 702.

The question is whether a court would admit the contrary opinion, that Ella works by impacting endometrial tissue and that on that basis, there is an effect on whether a fertilized egg can properly implant. That opinion is a tougher call both because (1) it is not a generally accepted view of how Ella works, (2) the opinion reflects an analytical gap between principles and facts, and (3) it could be argued that the opinion does not have sufficient facts or data to support it.

In any event, there is little question that a scientific opinion would be admitted which is contrary to the position offered by the *Hobby Lobby* plaintiffs (that Ella acts on a fertilized egg and that it prevents implantation of a fertilized egg).

C. Would the Court Have Admitted Evidence that Plan B (pill form of Levonorgestrel) Is or Is Not an Abortifacient?

Although Plan B has a checkered political history, the most recent prominent scientific research concludes with strong direct evidence that the pill prevents or delays ovulation and does not interfere with fertilization or affect implantation of the blastocyst. The FIGO statement cited eight studies that showed strong direct evidence that Plan B prevents or delays ovulation and is the primary mechanism of action for this contraceptive.¹⁸¹ As shown in the FIGO Statement, there are two studies that conclude emergency contraception does not affect implantation.¹⁸² These two studies were published in respected peer-reviewed scientific journals, one in *Contraception*, and the other, in *Human Reproduction*.¹⁸³ These are professional journals targeted to a medical audience and not concerned about the politics of contraceptives.

For example, *Contraception*'s editorial statement says its aim is to “advance reproductive health through the rapid publication of the best and most interesting new scholarship regarding contraception and related fields such as abortion.”¹⁸⁴ It is the official journal of the Association of Reproductive Health Professionals.¹⁸⁵ *Human*

¹⁸¹ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁸² International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁸³ International Federation of Gynecology & Obstetrics, *supra* note 124.

¹⁸⁴ CONTRACEPTION, <http://www.contraceptionjournal.org/content/authorinfo#idp1314592> (last visited Nov. 11, 2014).

¹⁸⁵ *Id.*

Reproduction is a similar journal published by Oxford, dedicated to “full-length, peer-reviewed papers reporting original research, concise clinical case histories, as well as opinions and debates on topical issues.”¹⁸⁶ Thus, by relying on research published in high quality medical journals, the opinion that Levonorgestrel is not an abortifacient is the product of reliable scientific research principles and methods.

Furthermore, these opinions are based on sufficient facts or data. All of the studies cited involved testing a hypothesis with data and analysis, and comparing the data with a control group. The tests were not funded by political action groups but rather were conducted by independent researchers with funding by universities or government grants. The researchers were required by their journals to disclose whether they had any conflicts of interests in conducting the research.

Indeed, each of these experts—as reflected in their publications and reports of their publications—has the ability to “give a dissertation or exposition of scientific . . . principles relevant to the case.”¹⁸⁷ There is no question that this view of how Plan B works would be admissible.

As with *Ella*, the question is whether an alternative view, supporting the position of the *Hobby Lobby* plaintiffs, would also be admitted. An expert may point to the manufacturer’s own packaging statement, that a post-fertilization effect is possible, even though the FDA required the manufacturer to place that statement on the label over the manufacturer’s objection that the statement was not scientifically justified. There is also the notion that Plan B may have endometrial effects, even if there is no direct evidence linking endometrial effects with disruption of implantation. Thus, it is not likely that the *Hobby Lobby* plaintiffs’ view of the science would be admitted, but it is possible. In that event, the fact-finder would receive both scientific views about how Plan B works and would have to evaluate which opinion about Plan B’s mechanism of action is more persuasive.

D. *Would the Court Have Admitted Evidence that IUDs Are or Are Not Abortifacients?*

The majority scientific view, based on facts and data published in well-regarded professional publications, is that IUDs work by preventing fertilization.¹⁸⁸ Interference with the reproductive process after fertilization has taken place is exceptional in the presence of a copper or LNG IUD.¹⁸⁹ Opinions that IUDs do not act on fertilized eggs and do not disrupt implantation of a fertilized egg would be based on scientific facts and data presented in reputable scientific publications, and based on scientific principles and methods subject to peer review.

While the view that IUDs interfere with the reproductive process after fertilization has taken place is not widely held, there are scientific articles that analyze research and reach this conclusion. With respect to copper-releasing IUDs, the opinion could be offered based on scientific analysis of research data that copper IUDs work both as a pre-

¹⁸⁶ HUMAN REPRODUCTION, http://www.oxfordjournals.org/our_journals/humrep/about.html (last visited Nov. 11, 2014).

¹⁸⁷ FED. R. EVID. 702, advisory committee’s note, 1972 Proposed rules.

¹⁸⁸ Ortiz, *supra* note 112.

¹⁸⁹ Ortiz, *supra* note 112.

fertilization spermicidal action and as a post-fertilization inhibition of uterine implantation. While the research is not current and the opinion not broadly held, nonetheless under Rule 702's focus on "sufficient facts or data" and "reliable principles and methods" it is likely that this opinion would be admitted.

With respect to LNG IUDs, while the general medical view is that these IUDs work by preventing fertilization, there is not full scientific agreement. Some of the disagreement is based on studies with a small number of patients, which may jeopardize the reliability of such opinions under Rule 702, with its emphasis on "sufficient facts or data" and "reliable principles and methods." However, it is generally agreed that studies of IUD effects are hard to complete on large number of patients, so opinions based on a small number of patients could be admitted.¹⁹⁰

In short, opinions that IUDs, whether copper-releasing or LNG-releasing, work before fertilization takes place are the prevailing scientific view and would likely be admitted under Rule 702. It is also likely that the countervailing view could also be admitted under Rule 702.

VI. HOW WOULD THE *HOBBY LOBBY* DECISION CHANGE IF RULE 702 HAD BEEN APPLIED?

If the trial court had performed a gatekeeping role, evidence that these four contested *Hobby Lobby* contraceptives were not abortifacients should have been admitted. This is not to say that competing evidence, taking the contrary view, would not have also been admitted.¹⁹¹ Of course, those contending that the four contraceptives are abortifacients would have the opportunity to buttress their belief with scientific evidence.¹⁹² The judge then would evaluate "whether expert testimony is sufficiently reliable to be considered by the trier of fact."¹⁹³ Ultimately, the judge or jury would then weigh the competing evidence and make a factual determination of whether each challenged contraceptive is an abortifacient. By neglecting the requirements of Rule 702, the *Hobby Lobby* trial and appellate judges apparently assumed that the four contraceptives at issue were abortifacients (with the exception of Judge Briscoe of the 10th Circuit).

The government's failure to challenge *Hobby Lobby's* premise that the contraceptives at issue were abortifacients should not dispose of the need for scientific proof. It is fundamental in litigation that the plaintiff has the burden of proof on every element of a claim. In both underlying *Hobby Lobby* cases, the plaintiffs claimed that the ACA imposed a substantial burden on the plaintiffs' religious exercise because the Act mandated "coverage or access to coverage of abortion-causing drugs or devices . . .

¹⁹⁰ Ortiz, *supra* note 112, at S17.

¹⁹¹ FED. R. EVID. 702, *supra* note 58 ("When a trial court, applying this amendment, rules that an expert's testimony is reliable, this does not necessarily mean that contradictory expert testimony is unreliable."); *see also* Ruiz-Troche v. Pepsi Cola, 161 F. 3d 77, 85 (1st Cir. 1998).

¹⁹² *In re Paoli R.R. Yard PCB Litigation*, 35 F. 3d 717, 744 (3d Cir. 1994)(holding that a party does not have to prove at the gatekeeping stage that its experts are correct, "they only have to demonstrate by a preponderance of evidence that their opinions are reliable . . . The evidentiary requirement of reliability is lower than the merits standard of correctness").

¹⁹³ FED. R. EVID. 702, *supra* note 58.

.”¹⁹⁴ Moreover, the *Hobby Lobby* plaintiffs did not simply object that their religious beliefs prevented coverage of all contraceptives. Rather, their claim focused on particular contraceptives that allegedly caused abortions. Therefore, to prevail, the plaintiffs should have been required by the trial courts, and by any reviewing courts, to prove with scientific evidence that each contraceptive at issue actually behaved in the way the plaintiffs alleged. Such proof was all the more vital in the context of a preliminary injunction, the procedure in both underlying cases, because a preliminary injunction is an “extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.”¹⁹⁵ In short, without the scientific foundation for showing whether the challenged contraceptives were indeed abortifacients, the plaintiffs failed to prove an essential element of their claim.

In this vein, Fed. R. Evid. 706 provides a procedure for a trial judge to appoint an expert to assist the court with its deliberations, whether or not the parties do so: “On a party’s motion or on its own, the court may order the parties to show cause why expert witnesses should not be appointed and may ask the parties to submit nominations. The court may appoint any expert that the parties agree on and any of its own choosing. But the court may only appoint someone who consents to act.”¹⁹⁶

If Rule 702 had been applied, the trial courts would have admitted scientific evidence about the mechanism of action for the four methods of contraceptives. That scientific evidence would become the basis to decide whether or not each method is an abortifacient, thereby providing expert scientific opinions for reaching a factual conclusion and properly challenging a major premise underlying the *Hobby Lobby* decisions.

A. Impact On The “Substantial Burden” Analysis

The finding that the *Hobby Lobby* plaintiffs’ claims were based on junk science would have a significant impact on the Court’s “substantial burden” analysis. In *Hobby Lobby*, where First Amendment and statutory religious freedom guarantees were at issue, the Court decided that the challenged HHS regulations requiring contraceptive coverage “substantially burdened the exercise of religion.”¹⁹⁷ The Court held that there was a substantial burden¹⁹⁸ on Hobby Lobby and Conestoga because they “have religious objections to abortions.”¹⁹⁹ Thus, they believed that by complying, they would “facilitate[e] abortions,” but that “if they do not comply, they will pay a very heavy price—as much as \$1.3 million per day, or about \$475 million per year, in the case of one of the companies.”²⁰⁰

¹⁹⁴ Complaint, *Hobby Lobby, Inc. v. Sebelius*, 2012 WL 4009450 (W.D. Okla. Sept. 12, 2012); First Amended Complaint, *Conestoga Wood Specialties Corp. v. Sebelius*, 2013 WL 6181041 (E.D. Pa. Jan. 11, 2013) (making a similar allegation: that “Plaintiffs’ sincerely held religious beliefs prohibit them from providing coverage for abortifacients and contraception with a possible abortifacient effect . . .”).

¹⁹⁵ *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008).

¹⁹⁶ FED. R. EVID. 706.

¹⁹⁷ *Burwell v. Hobby Lobby*, 134 S. Ct. 2751, 2759 (2014).

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

But a reexamination of the contraceptive mandate shows that, in fact, it did not actually infringe upon the corporations' sincerely held beliefs. If the trial court had applied Rule 702 to the *Hobby Lobby* respondents' claims, the Supreme Court's analysis could have totally changed in favor of the government. At a minimum, the record would contain substantial opinion evidence that none of these four contraceptives are abortifacients. In addition, it is possible that for two of the four contraceptives—Ella and Plan B—no contrary expert opinions would have been admitted. Thus, it is likely that the case would have come before the Supreme Court with a factual finding below that at least some, and perhaps all, of the challenged contraceptives were not abortifacients, and thus could not possibly infringe upon the companies' anti-abortion beliefs. Such a factual finding would have been entitled to great deference by the Court.

B. Does A Rule 702 Analysis Violate The Free Exercise Clause or RFRA?

A search of Westlaw reveals that no case has ever asked the question whether a Rule 702 analysis violates the Free Exercise Clause or RFRA. Under RFRA, the “Government shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability.”²⁰¹ The burdened person is entitled to an exemption unless the Government can demonstrate “that application of the burden to the person –1) is in furtherance of a compelling governmental interest 2) is the least restrictive means of furthering that compelling governmental interest.”²⁰²

Under a post-*Daubert* review of the facts, the government arguably has a much more compelling interest: to make sure that legal claims with scientific underpinnings are factually correct. We should not want our court systems to be filled with junk scientific claims about abortifacients, which would undermine the credibility of our legal system and set bad precedent. Additionally, there would be equal protection concerns if courts were lax in allowing junk science into the courtroom in cases about women’s reproductive freedom, but were more diligent about policing junk science in other cases. Certainly, the government has a compelling interest in ensuring that women are treated equally in accordance with the due process and equal protection clauses of both the Fifth and Fourteenth Amendments.

Furthermore, engaging in a Rule 702 analysis would not infringe on petitioners’ right to freely exercise their religious beliefs. Rather, the analysis would simply show whether the underlying facts support a claim that religious exercise has been burdened: a religious belief against abortion, no matter how sincere and compelling, is irrelevant if the contraceptives in question are not, in fact, abortifacients.

Even the dissenting opinion in the Supreme Court’s decision failed to fully analyze the lack of evidence under Rule 702. On the one hand, Justice Ginsburg alluded to the fact there is a lack of evidence showing that plaintiffs will be substantially burdened.²⁰³ She noted that “the Court barely pauses to inquire whether any burden imposed by the contraceptive coverage requirement is substantial.”²⁰⁴ But on the other hand, the analysis

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Id.* at 2798 (Ginsburg, J., dissenting).

²⁰⁴ *Id.*

falls short because it focused on how much the plaintiffs will need to pay the government in fines if they do not comply with the law, rather than the moral burden, which the dissent—like the majority—presumes.²⁰⁵ It is that moral burden that is unsupported by science, and should have been more closely scrutinized under Rule 702.

VII. CONCLUSION

Hobby Lobby is an example of how the Supreme Court neglected its own precedent. The Court should have remanded the case to the lower courts for further fact-finding, subject to a Rule 702 analysis, before reaching a decision about whether government action burdened religious beliefs where the alleged burden appears to be rooted in bad science. Instead, by ignoring the faulty assumptions underlying the *Hobby Lobby* plaintiffs' claims, the Court upset the important precedent of *Daubert* and reopened the risk of junk science in the courtroom.

Furthermore, the Court's decision may have consequences for public health policy in the United States and abroad. Unfortunately, the *Hobby Lobby* decision reinforces medical myths that IUDs and emergency contraceptives are abortifacients. These mistaken ideas could well undermine the ability of medical professionals to implement effective family planning outreach with safe and reliable forms of contraception.²⁰⁶ While this is not strictly a legal problem, courts have a responsibility to ensure that science is evaluated appropriately in the courtroom because decisions made inside the courtroom can have meaningful repercussions outside the courtroom as well. Moreover, the Court's precedent could lead lower courts to grant greater deference to religious plaintiffs' erroneous beliefs on secular, scientific questions.²⁰⁷

The Court is also setting a bad precedent and potentially disregarding the commands of the Fifth and Fourteenth Amendments when it allows matters related to women's bodies to be treated differently or with less scientific rigor in the courtroom. Why is it that Rule 702, which requires a trial judge to review all sorts of scientific testimony, is routinely applied in many different factual scenarios—from toxic torts to criminal cases involving DNA testing—but in this case, involving women's reproductive choices, it was ignored?

Of course, the initial responsibility to require scientific evidence, and then to apply Rule 702, lies with the trial judge. In neither of the two cases that were part of the *Hobby Lobby* decision did the federal district judges raise the issue that the plaintiffs had not proffered one bit of scientific evidence to back up their claims. Furthermore, the government did not raise the scientific argument. It was only when the case arrived at the Supreme Court that attorneys representing various physician groups raised the scientific issues, albeit as amici curiae.²⁰⁸ It is unclear why the government did not raise the issue: was it out of concern that raising the claim's lack of scientific validity might enrage religious conservatives? President Barack Obama was running a tough reelection

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 2788–89.

²⁰⁷ Though the *Hobby Lobby* plaintiffs' beliefs about abortion were religious, its belief that the contraceptives were abortifacients is a question of fact that can, and should, be answered by science alone.

²⁰⁸ Brief of Physicians For Reproductive Health, *supra* note 108.

campaign in 2012, just as the *Hobby Lobby* cases were making their way through the lower courts. Perhaps, in an effort to woo independent voters, his administration chose to quietly argue *Hobby Lobby* on less controversial grounds rather than aggressively attack the plaintiffs' professed religious beliefs as junk science.

If this theory is correct, however, it shows compellingly why trial judges must act on their responsibility to be the gatekeepers. If the adversaries themselves refuse to challenge the junk science—because of a lack of financial resources, or a lack of political will—the trial judge must be able to separate fiction from reality, upholding the integrity of the judiciary even when the parties do not. In short, it is the trial judge who can, and must, stop alchemy and astrology from running rampant and roughshod over the integrity of the courtroom.