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Legislating Morality Progressively - The Contraceptive Coverage Mandate, Religious Freedom, and Public Health Policy and Ethics

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**LEGISLATING MORALITY PROGRESSIVELY—
THE CONTRACEPTIVE COVERAGE MANDATE,
RELIGIOUS FREEDOM, AND PUBLIC HEALTH
POLICY AND ETHICS**

MICHAEL J. DEBOER*

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I. INTRODUCTION

In the area of reproductive rights in the United States, one of the biggest developments in the last several years has been the so-called contraceptive coverage mandate. The mandate requires employers, group health plans, and health insurance issuers to cover all United States Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling.¹ The Obama Administration chose to mandate this coverage in rules it promulgated, specifying the preventive health services for women that must be covered under the Affordable Care Act (ACA).²

¹ See *infra* Part II.

² On March 23, 2010, President Barack Obama signed the Patient Protection and Affordable Care Act (PPACA). Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). Then, on March 30, 2010, he signed the Health Care and Education Reconciliation Act (HCERA). Health Care and Education Reconciliation Act, Pub. L. No.

Since its promulgation, hundreds of citizens, businesses, and nonprofit and religious organizations have challenged the mandate in dozens of lawsuits, which are at various stages of litigation.³ The Supreme Court of the United States ruled on two cases that were brought by family-owned businesses that objected to four of the twenty FDA-approved contraceptives.⁴ Both Hobby Lobby Stores, Inc. (Hobby Lobby) and Conestoga Wood Specialties Corporation (Conestoga Wood) objected to two drugs, commonly known as “Plan B” and “Ella,” as well as to two intrauterine devices (IUDs) that operate after fertilization and prevent uterine implantation of fertilized eggs (human embryos), thus causing an abortifacient effect.⁵ Although Hobby Lobby and Conestoga Wood objected to paying for these four methods of contraception, they otherwise provided health insurance to their employees, including methods of contraception that they do not oppose on religious grounds.⁶

This Article studies the contraceptive coverage mandate from three different perspectives. First, it provides a historical treatment of the regulatory rules adopted by agencies in the Obama Administration – specifically, the Departments of the Treasury, Labor, and Health and Human Services, which this Article collectively refers to as “the Administration” or “the Departments” – that imposed the mandate, focusing specifically on the rulemaking processes used to develop and promulgate the rules. In performing this historical study, the Article traces the development of the mandate from its root in the ACA to full implementation in legislative (substantive) rules finalized by the Administration in the summer of 2013.⁷ Second,

111-152, 124 Stat. 1029 (2010). This Article will refer to these laws collectively as either the “Affordable Care Act” or the “ACA.” For a discussion of the relevant provisions of the ACA, the mandate, and the regulatory rules developed by the Administration that implement the mandate, see *infra* Part II.

³ See THE BECKET FUND FOR RELIGIOUS LIBERTY, <http://www.becketfund.org/hhs/informationcentral> (last visited Nov. 8, 2014) (accessible and comprehensive collection of cases and litigation documents); see also NATIONAL WOMEN’S LAW CENTER, <http://www.nwlc.org/status-lawsuits-challenging-affordable-care-acts-birth-control-coverage-benefit> (last visited Nov. 8, 2014) (survey of lawsuits and summaries of the status of pending cases).

⁴ *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). In *Hobby Lobby Stores*, the Court affirmed the Tenth Circuit’s ruling in *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013), and reversed and remanded the ruling of the Third Circuit in *Conestoga Wood Specialties Corp. v. Burwell*, 724 F.3d 377 (3d Cir. 2013). See also *Burwell v. Hobby Lobby Stores, Inc.*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/sebelius-v-hobby-lobby-stores-inc> (last visited Nov. 8, 2014) (materials and commentary relating to the Hobby Lobby Stores case); see also *Conestoga Wood Specialties Corp. v. Burwell*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/conestoga-wood-specialties-corp-v-sebelius> (last visited Nov. 8, 2014) (materials and commentary relating to the Conestoga Wood Specialties case).

⁵ Brief for Respondents at *4, *sub nom* *Sebelius v. Hobby Lobby Stores, Inc.*, 2014 WL 546899 (No. 13-354); Brief for Petitioners at *4, *sub nom* *Conestoga Wood Specialties Corp. v. Sebelius*, 2014 WL 173487 (No. 13-356).

⁶ See Brief for Petitioners at *5, *Conestoga Wood Specialties Corp. v. Sebelius*, 2014 WL 173487 (No. 13-356); Petition for Writ of Certiorari at *1, *Conestoga Wood Specialties Corp. v. Sebelius*, 2013 WL 5291412 (No. 13-356); see also *Hobby Lobby Media Information and Fact Sheet*, THE BECKET FUND FOR RELIGIOUS LIBERTY, <http://www.becketfund.org/hobby/lobbyfactsheet> (last visited Nov. 8, 2014).

⁷ See *infra* Part II.

this Article evaluates the mandate under the legal framework established by Congress in the Religious Freedom Restoration Act (RFRA),⁸ focusing especially on the Administration's RFRA analysis in its rulemaking materials and the Supreme Court's recent ruling regarding the mandate.⁹ Third, it analyzes the mandate under a moral and policy-based framework proposed by a team of leading bioethicists, public health policy analysts, and scholars. It applies the team's proposed framework to determine whether the Departments that developed and adopted the mandate satisfied the various moral and policy considerations that these experts have highlighted.¹⁰

The analyses in this Article will establish the following four points:

- (1) The Administration chose to employ regulatory procedures that failed to ensure transparency, hindered meaningful public participation, hampered dialogue between policymakers and interested individuals and organizations, and deprived the public of the deliberative process agency rulemaking is supposed to afford.
- (2) In its rulemaking, the Administration's consideration of the First Amendment and RFRA was cursory and untimely. Consequently, the Administration failed adequately to consider the religious freedom implications of creating by regulatory rule a positive right to coverage that conflicted with a negative right grounded in the First Amendment that Congress had reinforced in RFRA.
- (3) In developing the mandate, the Administration failed adequately to address basic moral and policy considerations that provide concrete guidance for evaluating and justifying public health initiatives. Consequently, the Administration's deliberations about and justifications for this public health initiative were unsatisfactory, failing adequately to resolve conflicts that the initiative created among general moral considerations.
- (4) In adopting the regulatory rules and imposing the mandate, the Administration "legislated" its conception of morality. The mandate does not simply represent the policy judgments of the policymakers, but also the moral judgments of the policymakers based upon their progressive moral vision and values.¹¹ Thus, although the mandate is framed in regulatory,

⁸ Religious Freedom Restoration Act of 1993, Pub. L. No. 13-141, 107 Stat. 1488 (1993).

⁹ See *infra* Part III.

¹⁰ See *infra* Part IV.

¹¹ The aim of this Article is not to explicate progressive morality, nor to explore its ideological foundations, nor to trace its contours. Rather, it is to analyze the mandate from three perspectives. In the process, however, this Article will reveal that moral decision-making undergirds the mandate. The term "progressive" here refers to a set of ideological, moral, and political beliefs and values shared by proponents of a current movement as well as proponents of an earlier movement in United States history. The earlier movement, which historians identify with the Progressive Era of the late 19th and early 20th centuries, altered the American landscape in fundamental ways, and its effects were felt in all sectors of society and culture—business, education, government, law, religion, and science. See *generally* LEWIS L. GOULD, *AMERICA IN THE PROGRESSIVE ERA, 1890–1914* (2001); *THE PROGRESSIVE ERA* (Lewis L. Gould, ed., 1974); WALTER NUGENT, *PROGRESSIVISM: A VERY SHORT INTRODUCTION* (2010); Daniel T. Rogers, *In Search of Progressivism*, 10 *REV. AM. HIST.* 113 (1982). In government and law, the Progressives manifested great confidence that "unbiased" physical and social sciences and technical expertise, reason and decisions based upon empirical data,

public health, social scientific, and medical terminology, it advances a particular moral vision, is premised upon the moral values held by the policymakers, and reflects their conception of what is “good” and what constitutes a “good society.”¹²

and government, its administrative apparatus, and “administratively organized ‘communities’ of highly trained, objective professionals” would lead society forward and bring about transformative social, legal, and economic reforms. Joel D. Schwartz, *Book Review, Liberty, Democracy, and the Origins of American Bureaucracy*, 97 HARV. L. REV. 815, 820 (1984). For the Progressives, science, expertise, and administration held the promise of the future, and the interests of businesses and business owners and the concerns of lay people were understood as obstacles to the desired progress. See generally RICHARD L. MCCORMICK, *THE PARTY PERIOD AND PUBLIC POLICY: AMERICAN POLITICS FROM THE AGE OF JACKSON TO THE PROGRESSIVE ERA* (1988); WILLIAM E. NELSON, *THE ROOTS OF AMERICAN BUREAUCRACY 1830-1900* (1982); MARTIN SHAPIRO, *WHO GUARDS THE GUARDIANS?: JUDICIAL CONTROL OF ADMINISTRATION* (1988); DWIGHT WALDO, *THE ADMINISTRATIVE STATE: A STUDY OF THE POLITICAL THEORY OF AMERICAN PUBLIC ADMINISTRATION* (1984); ROBERT H. WIEBE, *THE SEARCH FOR ORDER 1877-1920* (1967); Gerald E. Frug, *The Ideology of Bureaucracy in American Law*, 97 HARV. L. REV. 1276 (1984); Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189 (1986). As for the current manifestation of progressivism, scholars on both the left and the right have begun to identify a progressive movement currently underway. See Charles Murray, *The Trouble Isn’t Liberals. It’s Progressives*, WALL STREET J. (July 1, 2014) (“[P]rogressive intellectuals [a century ago] were passionate advocates of rule by disinterested experts led by a strong unifying leader. They were in favor of using the state to mold social institutions in the interests of the collective. They thought that individualism and the Constitution were both outmoded. . . . It is that core philosophy extolling the urge to mold society that still animates progressives today—a mindset that produces the shutdown of debate and growing intolerance that we are witnessing in today’s America. Such thinking on the left also is behind the rationales for indulging President Obama in his anti-constitutional use of executive power. . . . [W]e should start using ‘liberal’ to designate the good guys on the left, reserving ‘progressive’ for those who are enthusiastic about an unrestrained regulatory state, who think it’s just fine to subordinate the interests of individuals to large social projects, who cheer the president’s abuse of executive power and who have no problem rationalizing the stifling of dissent.”); Jeffrey D. Sachs, *The New Progressive Movement*, N.Y. TIMES (Nov. 12, 2011) (“Following our recent financial calamity, a third progressive era is likely to be in the making. This one should aim for three things. The first is a revival of crucial public services, especially education, training, public investment and environmental protection. The second is the end of a climate of impunity that encouraged nearly every Wall Street firm to commit financial fraud. The third is to re-establish the supremacy of people votes over dollar votes in Washington. . . . The new movement also needs to build a public policy platform. The American people have it absolutely right on the three main points of a new agenda. To put it simply: tax the rich, end the wars and restore honest and effective government for all.”)

¹² From its inception, the recent health care reform effort in the United States that culminated in the enactment of the ACA has seemingly been inspired by a particular moral vision. In a letter to President Obama written nearly ten months before the President signed the ACA into law, the late Senator Edward Kennedy highlighted their shared commitment to health care reform. See Letter from Senator Edward M. Kennedy to President, Barack Obama (May 12, 2009), http://www.whitehouse.gov/the_press_office/Text-of-letter-to-the-President-from-Senator-Edward-M-Kennedy. Senator Kennedy observed that health care “concerns more than material things; . . . what we face is above all a moral issue; . . . at stake are not just the details of policy, but fundamental principles of social justice and the character of our country.” *Id.*

II. STATUTORY AND REGULATORY BACKGROUND REGARDING THE CONTRACEPTIVE COVERAGE MANDATE

A. *The Relevant Affordable Care Act Provisions*

The ACA did not mandate that employers and health insurance plans cover contraceptives, sterilization, or patient education and services. Rather, the ACA required group health plans and health insurance issuers offering group or individual health insurance coverage to cover several broad categories of preventive health services.¹³ The following were among the required preventive health services:

- (1) Evidence-based items or services recommended with a rating of A or B by the United States Preventive Services Task Force (USPSTF),¹⁴ and
- (2) As to women, preventive care and screenings (in addition to those items and services recommended by the USPSTF) provided for in comprehensive guidelines supported by the U.S. Health Resources and Services Administration (HRSA).¹⁵

¹³ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1001, 124 Stat. 131 (codified at 42 U.S.C. § 300gg-13 (2012)).

¹⁴ *Id.* See *About the USPSTF*, U.S. PREVENTIVE SERVICES TASK FORCE, <http://www.uspreventiveservicestaskforce.org/Page/Name/about-the-uspstf> (last visited Nov. 9, 2014). The USPSTF is an independent, volunteer panel of primary care providers with expertise in prevention and evidence-based medicine. *Id.* The task force conducts scientific evidence reviews of clinical preventive services (such as screenings, counseling, and preventive medications) and makes recommendations for primary care clinicians and health systems. Janelle Guirguis-Blake, et al., *Current Processes of the U.S. Preventive Service Task Force: Refining Evidence-Based Recommendation Development*, 147 ANNALS OF INTERNAL MEDICINE 117, 117 (2007), available at <http://www.uspreventiveservicestaskforce.org/Home/GetFile/6/7/currprocess/pdf>. The Agency for Healthcare Research and Quality (AHRQ) within the Department of Health and Human Services (HHS) provides the task force administrative, research, technical, and dissemination support. See *id.* The Director of AHRQ appoints new USPSTF members, with guidance provided by the Chair of the task force. *U.S. Preventive Services Task Force (USPSTF): An Introduction*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/uspstf/index.html> (last visited Nov. 9, 2014).

¹⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1001, 124 Stat. 131 (codified at 42 U.S.C. § 300gg-13 (2012)). HRSA is an agency within HHS that seeks to improve access to health care services. See *About HRSA*, HEALTH RES. & SERVS. ADMIN., <http://www.hrsa.gov/about/index.html> (last visited Nov. 9, 2014). This particular provision (the Women's Health Amendment) was added to the bill that became the ACA in the Senate. Proponents of this provision thought that this additional coverage mandate for women would fill a gap in the initially proposed version of the preventive health services coverage mandate. Press Release, Sen. Barbara A. Mikulski, Mikulski Puts Women First in Health Care Reform Debate: Senator Introduces First Amendment to Senate Health Care Reform Bill to Guarantee Women Access to Preventive Screenings and Care at No Cost (Nov. 30, 2009), <http://www.mikulski.senate.gov/newsroom/press-releases/mikulski-puts-women-first-in-health-care-reform-debate>. See also 155 Cong. Rec. 28841, 29070 (2009) (statements of Senators Boxer and Mikulski).

The ACA prohibited the imposition of cost-sharing requirements (e.g., copayments, coinsurance, and deductibles) as to these covered items and services.¹⁶ As the grandfathered status of health plans is lost over time, most health plans and health insurance issuers (and employers) will be required to cover the specified preventive services free of charge to beneficiaries and employees.¹⁷

B. The Regulations

Subsequently, the Obama Administration adopted regulatory rules implementing these provisions of the ACA. It was in these rulemakings that the Administration decided to include all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling within the required package of covered preventive health services.

1. The July 2010 Interim Final Rulemaking

In July 2010, about four months after the ACA was enacted,¹⁸ the Administration issued a set of interim final rules.¹⁹ These interim final rules, consistent with the ACA, required health plans and health insurance issuers to provide coverage of the following relevant categories of items and services:

- (1) Evidence-based items and services recommended by the USPSTF with a rating of A or B; and
- (2) For women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by the HRSA.²⁰

¹⁶ See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1001, 124 Stat. 131 (2010) (codified at 42 U.S.C. § 300gg-13 (2012)). The ACA elsewhere specifies that the term “cost-sharing” includes: “deductibles, coinsurance, copayments, or similar charges,” and “any other expenditure required of an insured individual which is a qualified medical expense . . . with respect to essential health benefits covered by the plan.” *Id.* at § 1302(c)(3)(A) (codified at 42 U.S.C. § 18022(c)(3)(A)).

¹⁷ See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1251, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18011). The Departments’ regulatory materials indicate that the grandfathered status under the ACA “is only transitional in effect, and [that] it is expected that a majority of plans will lose their grandfathered status by the end of 2013.” See also Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,887 n.49 (July 2, 2013) [hereinafter *July 2013 Final Rules*].

¹⁸ President Obama signed the ACA on March 23 and the HCERA on March 30 of 2010. See *supra* note 2.

¹⁹ See Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726, 41,728 (July 19, 2010) [hereinafter *Interim Final Rules*]. In the regulatory materials, the Departments indicated that they were issuing other interim final rules to implement various provisions of the ACA, including: the provision requiring dependent coverage of children to age 26; the provision relating to status as a grandfathered health plan; and the provisions prohibiting preexisting condition exclusions, regarding lifetime and annual dollar limits on benefits, regarding restrictions on rescissions, and regarding patient protections. *Id.*

²⁰ *Id.* at 41,756–59.

The regulatory materials indicated that the Department of Health and Human Services (HHS) was developing comprehensive guidelines for preventive care and screening for women and expected to issue them no later than August 1, 2011.²¹

These interim final rules were effective on September 17, 2010, the same date comments from the public and interested persons were due.²² The Departments' decision to issue interim final rules, instead of following the standard notice-and-comment process that would have ensured meaningful public participation and full vetting of the rules before they went into effect,²³ meant that the rules would be effective without comments from the public on any proposed rules being reviewed and considered by the Departments prior to the effective date.²⁴ The Administration justified its decision to sidestep standard rulemaking procedures and instead to use the truncated rulemaking process on the following two grounds:

- (1) Statutory grounds in the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act;²⁵ and
- (2) Good cause because "a full public notice and comment process" was impracticable and contrary to the public interest.²⁶

The Departments' position was thus that they had statutory authority to employ the interim final rulemaking process and that the good cause exception to notice-and-comment rulemaking applied. Citing provisions of the ACA, the Departments asserted that this expedited rulemaking process was necessary to ensure that the regulations would be in place for plan years and policy years beginning on or after September 23, 2010, and that coverage would be implemented on a timely basis.²⁷ Accordingly, the Departments determined to push the rules through, even though it meant that public participation would be restricted and that their consideration of the feedback received from the public regarding the rules would be delayed by nearly a year.

²¹ *Id.* at 41,728.

²² *Id.* at 41,726.

²³ Under the Administrative Procedure Act (APA), agencies ordinarily adopt regulations pursuant to standard rulemaking procedures that require agencies (1) to give the public and interested persons notice of proposed rules, (2) to afford the public opportunity to comment on (i.e., participate in the rulemaking and give feedback regarding) proposals, and (3) to review the feedback received, modify proposals based upon the feedback, state in writing the reasons for adopting the final version of the rules, and issue the final rules. Upon issuing final rules, agencies specify the effective date. *See* 5 U.S.C. § 553. The APA provides some exceptions to these procedural requirements, including the good cause exemption when notice and the public procedure are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. § 553(a), (b)(A), & (b)(B).

²⁴ *See* Michael Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 ADMIN. L. REV. 703, 704 (1999) ("Interim-final rules are rules adopted by federal agencies that become effective without prior notice and public comment and that invite post-effective public comment [The interim-final] rule is effective immediately but it also serves as a notice of proposed rulemaking for the final rule that will supplant it.").

²⁵ *See Interim Final Rules*, *supra* note 19, at 41,729–30 (listing as relevant federal statutes 26 U.S.C. § 9833 (2012), 29 U.S.C. § 1191c (2012), 42 U.S.C. § 300gg-92 (2012)).

²⁶ *See Interim Final Rules*, *supra* note 19, at 41,730 (citing 5 U.S.C. § 553(b) (2012)).

²⁷ *Id.*

It quickly became apparent that aspects of the HRSA guidelines being developed by HHS would be controversial. Upon the Departments' issuance of the interim final rules and public announcement regarding the development of the guidelines, the Planned Parenthood Federation of America launched its campaign to ensure that the guidelines would require coverage of family planning and all FDA-approved contraceptives with no cost-sharing.²⁸ Two months later, the United States Conference of Catholic Bishops (USCCB) urged the Administration not to include coverage of contraception and sterilization in the list of preventive services that group and individual health plans must cover.²⁹

2. The Institute of Medicine Committee Recommendations

Although the interim final rules did not mandate coverage of contraceptive and sterilization services, the rulemaking paved the way by requiring health plans and health insurance issuers to cover evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by HRSA. The Departments indicated that the guidelines were in development and expected by August 1, 2011.³⁰ The HHS Office of the Assistant Secretary for Planning and Evaluation provided funds for the Institute of Medicine (IOM) to convene a committee to conduct a

²⁸ See Press Release, Planned Parenthood Fed'n of America, Planned Parenthood Supports Initial White House Regulations on Preventive Care; Highlights Need for New Guidelines on Women's Preventive Health to Include Family Planning (July 14, 2010), <http://www.plannedparenthood.org/about-us/newsroom/press-releases/planned-parenthood-supports-initial-white-house-regulations-preventive-care-highlights-need-new>. When the interim final rules were issued, Planned Parenthood was ready to go with its campaign, and it was fortunate to have individuals friendly to its viewpoint well-positioned within HHS. Reports have shown that Kathleen Sebelius, the HHS Secretary who approved the mandate, had longstanding ties to and received political contributions from the late George Tiller, a Kansas doctor well-known for performing late-term abortions. See Deanna Candler, *The Advisors Behind the Contraceptive Mandate*, LIVE ACTION BLOG (Feb. 24, 2012), <http://liveaction.org/blog/the-advisors-behind-the-contraception-mandate/>; Penny Starr, *Sebelius: 'Keeping Our Children Safe . . . Most Fundamental Task'*, CNSNEWS.COM (May 7, 2013), <http://cnsnews.com/news/article/sebelius-keeping-our-children-safe-most-fundamental-task>. Additionally, Washington, D.C. attorney and former drug lobbyist William B. Schultz, whose clients at Zuckerman Spaeder LLP included Barr Laboratories, the maker of Plan B, became HHS's principal deputy general counsel and acting general counsel in 2011 and HHS's general counsel in 2013. See Timothy P. Carney, *Obama Nominates Ex-drug Lobbyist as Top HHS Lawyer*, WASHINGTON EXAMINER (Dec. 19, 2012), <http://www.washingtonexaminer.com/tim-carney-obama-nominates-ex-drug-lobbyist-as-top-hhs-lawyer/article/2516459>; Steven Ertelt, *Obama Names Lobbyist for Plan B Drug as Top HHS Lawyer*, FREE REPUBLIC (Dec. 20, 2012), <http://www.freerepublic.com/focus/f-news/2971046/posts>; U.S. Department of Health & Human Services, Press Release, *HHS Secretary Sebelius Announces Senate Confirmation of William B. Schultz, Nominee for General Counsel, Department of Health and Human Services* (Apr. 26, 2013), <http://www.hhs.gov/news/press/2013pres/04/20130426a.html>.

²⁹ Press Release, U.S. Conference of Catholic Bishops, *USCCB Officials Urge HHS Not to Require Coverage of Contraception and Sterilization* (Sept. 20, 2010), <http://usccb.org/news/2010/10-162.cfm>.

³⁰ See *supra* note 21 and accompanying text.

review of what preventive services are necessary for women's health and well-being and what services should be considered in developing comprehensive guidelines.³¹

The IOM Committee on Preventive Services for Women was formed to develop recommendations to fill possible gaps in recommended preventive services.³² The sixteen-member committee held five meetings over a six-month period and conducted three open sessions for presentations by invited stakeholders, women's health experts, and reproductive rights advocates and to hear from members of the public.³³ Pro-choice and reproductive-choice advocates and interest groups such as Planned Parenthood, the Guttmacher Institute, and the National Women's Law Center were well-represented among the committee members and the invited presenters.³⁴

On July 19, 2011, the Committee issued a 235-page report that included various recommendations.³⁵ The Committee recommended that eight preventive health services for women be added to the services that health plans must cover at no cost to patients.³⁶ Among them was a recommendation that the full range of "FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling (i.e., family planning services) for women" with reproductive capacity be covered.³⁷ For this recommendation, the Committee's express objectives were "preventing unintended pregnancy and promoting healthy birth spacing."³⁸

One member, Anthony Lo Sasso, Ph.D., dissented from the committee report, expressing concern that the compressed period of time prevented the Committee from conducting a serious, systematic review of all evidence for preventive services.³⁹ Beyond the time constraints, he noted that the Committee's process "lacked transparency and was largely subject to the preferences of the Committee's

³¹ See COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN, INSTITUTE OF MEDICINE, CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 1–2 (2011) [hereinafter CLOSING THE GAPS REPORT].

³² *Id.* at 2.

³³ *Id.* at v–vi, 217–21, 223–30.

³⁴ See *id.* at 223–30 (referencing Appendix C and biographies provided by the Committee regarding members Dr. Angela Diaz, Dr. Francisco Garcia, Dr. Paula A. Johnson, and Dr. Alina Salganicoff, which fail to note the prior advocacy and interest group affiliations and memberships of these individuals); see *id.* at 218–19 (identifying several invited presenters); see also Helen M. Alvaré, *No Compelling Interest: The "Birth Control" Mandate and Religious Freedom*, 58 VILL. L. REV. 379, 430 (2013) (citing Letter from Anna Franzonello, Staff Counsel, Ams. United for Life, to Ctrs. for Medicare and Medicaid Servs. (Sept. 29, 2011) (on file at www.freedom2care.org/docLib/20110929_AmericansUnitedforLife_preventiveservicescomment.pdf)).

³⁵ See CLOSING THE GAPS REPORT, *supra* note 31, at ix–x; see also Press Release, Institute of Medicine of the National Academies of Science, *Report at a Glance* (July 19, 2011), <http://www.iom.edu/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/Press-Release.aspx>.

³⁶ See CLOSING THE GAPS REPORT, *supra* note 31, at 1, 7–12.

³⁷ *Id.* at 10, 109–10.

³⁸ *Id.* at 102.

³⁹ See *id.* at 231.

composition,” in which “a mix of objective and subjective determinations [were] filtered through a lens of advocacy.”⁴⁰

3. The HRSA August 2011 Comprehensive Guidelines

Soon thereafter, HRSA adopted the IOM Committee’s recommendations and issued the Women’s Preventive Services Guidelines.⁴¹ Under the HRSA-supported coverage guidelines, non-grandfathered plans are generally required to cover various preventive services without cost sharing, including the following: “All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.”⁴²

4. The August 2011 Amended Interim Final Rulemaking

The Departments then issued amended interim final rules.⁴³ These rules reiterated the requirement that health plan coverage must include preventive care and screenings provided for in binding comprehensive guidelines supported by HRSA.⁴⁴ In this rulemaking, and for the first time, the Administration addressed the considerable volume of comments submitted by the public and interested persons regarding the first set of interim final rules.⁴⁵ Some of the commenters raised concerns regarding the requirement that religious employers cover contraceptive services that might be objectionable on religious grounds.⁴⁶

In these rules, the Departments acknowledged the appropriateness of HRSA considering the effect of a coverage mandate on the religious beliefs of certain employers when employees in “certain religious positions participate,” and they expressed a willingness to “provide for a religious accommodation that respects the unique relationship between a house of worship and its employees in ministerial positions.”⁴⁷ Accordingly, the Departments granted HRSA discretion to establish an exemption for certain religious employers as to contraceptive coverage.⁴⁸ The

⁴⁰ *Id.* at 232.

⁴¹ Health Res. and Serv. Admin., U.S. Dep’t of Health and Human Servs., *Affordable Care Act Expands Prevention Coverage for Women’s Health and Well-Being*, HRSA.GOV, <http://www.hrsa.gov/womensguidelines> (last visited Nov. 9, 2014).

⁴² *Id.* See also Press Release, Dep’t of Health and Human Servs., *Affordable Care Act Ensures Women Receive Preventive Services at No Additional Cost* (Aug. 1, 2011) (on file at <http://www.hhs.gov/news/press/2011pres/08/20110801b.html>).

⁴³ Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621 (Aug. 3, 2011) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147) [hereinafter *Amended Interim Final Rules*].

⁴⁴ *Id.* at 46,625–26.

⁴⁵ See *id.* at 46,623 (stating that the public had provided “considerable feedback regarding which preventive services for women” should be covered).

⁴⁶ See *id.*

⁴⁷ *Id.*

⁴⁸ See *id.* at 46,623; *id.* at 46,626 (granting HRSA discretion to “establish exemptions from [the] guidelines with respect to [] plans established or maintained by religious employers” and from “coverage provided in connection with [] plans established or

Departments defined the term “religious employer” narrowly for purposes of the mandate, requiring an employer to meet the following to qualify for the exemption:

- (1) The inculcation of religious values must be the purpose of the organization;
- (2) The organization must primarily employ persons who share the religious tenets of the organization;
- (3) The organization must primarily serve persons who share the religious tenets of the organization; and
- (4) The organization must be a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.⁴⁹

The Departments adopted this narrow definition in an effort to “reasonably balance” their goal of extending coverage to as many women as possible while respecting “the unique relationship between certain religious employers and their employees in certain religious positions.”⁵⁰

The Administration again chose to employ the interim final rulemaking process, rather than the standard notice-and-comment rulemaking process.⁵¹ Unlike the interim final rules issued one year earlier,⁵² the amended interim final rules were effective immediately on August 1, 2011, and comments were due sixty days later on September 30, 2011.⁵³ The Departments again justified their use of the truncated rulemaking process by citing federal statutory authority.⁵⁴ Additionally, in the Departments’ view, the policy behind the generally required notice-and-comment process was satisfied by virtue of the public having had opportunity to comment on the initial interim final rules, and the amendments being made in the amended interim final rules were based on the public comments they received.⁵⁵ Furthermore, the Departments concluded, “an additional opportunity for public comment on the amended interim final rules before they were made effective was impracticable and contrary to the public interest.”⁵⁶ Providing such an additional opportunity for public comment would, in the Administration’s view, delay coverage for another year because many plan years and policy years begin in August or September.⁵⁷ Similarly, the Departments asserted that good cause existed for waiving the general requirement that final rules be made effective no sooner than thirty days after they

maintained by religious employers with respect to any requirement to cover” the mandated services); *see also* U.S. Dep’t of Health and Human Servs., *supra* note 41.

⁴⁹ *Amended Interim Final Rules*, *supra* note 43, at 46,623.

⁵⁰ *Id.*

⁵¹ *Id.* at 46,621.

⁵² *See supra* Part II.B.1.

⁵³ *Amended Interim Final Rules*, *supra* note 43, at 46,621.

⁵⁴ *Id.* at 46,624.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

are published, and thus waived the thirty-day delay requirement, making the rules effective immediately.⁵⁸

5. The February 2012 Final Rulemaking

In February 2012, the Departments finalized their interim final rules.⁵⁹ In these “final-final rules”⁶⁰ regarding coverage of preventive services, the Departments made no changes to their interim final rules,⁶¹ despite the fact that the Departments received over 200,000 comments, and despite the lawsuits instituted challenging the mandate.⁶² The Administration’s decision to retain the narrow definition for the exemption for religious employers occurred after a November 2011 meeting between President Obama and then-Archbishop Timothy Dolan, who was serving as president of the USCCB.⁶³ At this meeting, President Obama indicated that he takes the protection of the rights of conscience with the “utmost seriousness,” and that he did not want to impede the Catholic Church’s work.⁶⁴ The final rules were effective on April 16, 2012.⁶⁵

The 200,000-plus responses were submitted by an array of individuals and organizations with different perspectives, and they raised a range of concerns, both in favor of and in opposition to the Administration’s narrow religious-employer exemption.⁶⁶ Some commenters suggested that the religious-employer exemption should be rescinded in its entirety so that benefits could extend to as many women as possible, and others, for the same reason, maintained that the exemption and the

⁵⁸ *Id.*

⁵⁹ See Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8725 (Feb. 15, 2012) [hereinafter *Final Rules*].

⁶⁰ See Asimow, *supra* note 24, at 705 (providing description of “final-final” and “interim-final” rule terminology).

⁶¹ *Final Rules*, *supra* note 59, at 8725.

⁶² *Id.* at 8,726. Belmont Abbey College in Belmont, North Carolina, and Colorado Christian University in Lakewood, Colorado, brought two early lawsuits challenging the mandate. Their lawsuits were filed in November 2011 and December 2011, respectively. The Becket Fund for Religious Liberty, Press Release, Belmont Abbey College Sues the Federal Government over New Obamacare Mandate (Nov. 10, 2011), <http://www.becketfund.org/wp-content/uploads/2011/11/Press-Release-HHS-Final11.10.11.pdf>; The Becket Fund for Religious Liberty, Press Release, Colorado Christian University First Evangelical University to Fight Abortifacient Mandate (Dec. 21, 2011), <http://www.becketfund.org/?p=3304&preview=true>. For copies of the complaints filed in these cases, see Belmont Abbey College v. Sebelius, Case No. 1:11-cv-01989 (D.D.C. 2011), <http://www.becketfund.org/wp-content/uploads/2011/11/HHS-Complaint-Final11.10.11.pdf>, and Colorado Christian University v. Sebelius, Case No. 11-cv-03350 (D. Colo. 2011), <http://www.becketfund.org/wp-content/uploads/2011/12/CCU-v-Sebelius-Complaint-final.pdf>.

⁶³ James Taranto, *When the Archbishop Met the President*, WALL ST. J., (Mar. 31, 2012), <http://online.wsj.com/news/articles/SB10001424052702303816504577311800821270184>.

⁶⁴ *Id.* For additional discussion of this meeting, see *infra* Part IV.C.2.c.

⁶⁵ *Final Rules*, *supra* note 59, at 8725.

⁶⁶ *Id.* at 8726.

definition of religious employer should not be broadened.⁶⁷ The following arguments were among those submitted in favor of expanding the exemption and broadening the definition of religious-employer: requiring organizations to pay for contraceptive services would compel them to act contrary to their religious beliefs; federal laws have provided for conscience clauses and religious exemptions broader than the currently contemplated exemption; and the narrow scope of the exemption raises concerns under the First Amendment and RFRA.⁶⁸ Commenters also suggested alternative definitions of religious employer.⁶⁹

In addition to issuing this final-final rule adopting the narrowly defined exemption, the Administration announced that it would afford a one-year enforcement safe harbor to some non-exempt, nonprofit organizations with religious objections.⁷⁰ The Departments indicated that, during the safe-harbor period, they would develop and propose changes to the rules to meet two goals: (1) “providing contraceptive coverage without cost-sharing to individuals who want it,” and (2) “accommodating non-exempted, non-profit organizations’ religious objections to covering contraceptive services.”⁷¹ The Departments anticipated developing new rules that would “require issuers to offer insurance without contraception coverage to such an employer (or plan sponsor) and simultaneously to offer contraceptive coverage directly to the employer’s plan participants (and their beneficiaries) who desire it, with no cost-sharing.”⁷²

In justifying their decision to finalize the interim final rules without any change, the Departments listed various beneficial results expected from the mandated coverage including:

- (1) Greater use of preventive services yields a healthier population and reduces health care costs;
- (2) Women have unique health care needs (such as contraceptive services) and burdens;
- (3) Women who are not immediately aware of a pregnancy and who experience unintended pregnancy may delay receiving prenatal care and continue to engage in high-risk behaviors and are at risk of preterm birth and low birth weight;
- (4) For some women, pregnancy is contraindicated;
- (5) Contraceptive use provides preventive health benefits relating to conditions other than pregnancy; and

⁶⁷ *Id.* at 8726–27.

⁶⁸ *Id.* at 8727; *see also* Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.* (2012).

⁶⁹ *Final Rules*, *supra* note 59, at 8725.

⁷⁰ *Id.* at 8727–28; *see* Taranto *supra* note 63 (suggesting that this safe harbor, in Archbishop Dolan’s view, simply gave religious institutions one year to figure out how they would violate their consciences). Additionally, the political effect of the one-year safe harbor was to release some pressure and delay some fallout from the mandate until after the 2012 presidential election. *See infra* note 139.

⁷¹ *Final Rules*, *supra* note 59, at 8727.

⁷² *Id.* at 8728.

- (6) Employers will experience cost savings by avoiding medical costs related to pregnancy and indirect costs related to employee absences and reduced productivity.⁷³

The Departments also identified several social concerns and goals behind their decision to mandate coverage of these services:

- (1) The unique health needs of women place them at a disadvantage in the workforce compared to male coworkers;
- (2) Access to contraception improves the social and economic status of women;
- (3) Contraceptive coverage eliminates disparities in the workforce by allowing women to achieve equal status as healthy and productive members of the job force by reducing the number of unintended pregnancies and potentially unhealthy pregnancies;
- (4) Cost sharing can be a significant barrier to effective contraception; and
- (5) Providing women broad access to preventive services, including contraceptive services, will reduce disparities.⁷⁴

As to the scope of the religious-employer exemption, the Departments stated that the exemption as adopted did not undermine the benefits of the mandated coverage because the narrow definition of religious employer helped to ensure that the employees affected would already share the employer's beliefs.⁷⁵ Additionally, in their view, a broader exemption would result in more employees having to pay out of their own pockets for contraceptives and fewer employees using contraceptive services, which would undermine the claimed benefits of the preventive services.⁷⁶ The Departments also expressed concern that expanding the scope of the religious-employer exemption would subject employees to the religious views of their employers, limit access to contraceptives, and inhibit the use of such services.⁷⁷

The Departments concluded their discussion of the reasons supporting their final rules by briefly addressing conscience and religious freedom. The Departments believed that their rules did not undermine conscience or conscience protections because the rules neither prevented employers or others from expressing their opposition to contraceptive use, nor compelled use of contraceptives, nor required health care providers to prescribe contraceptives.⁷⁸ Additionally, in their view, the rules did not undermine conscience protections or religious exemptions recognized in other federal laws; rather, they asserted, such protections would "be respected" and "strongly enforced."⁷⁹ The Departments briefly considered the First Amendment and RFRA, opining that their approach in the rules was consistent with both.⁸⁰

⁷³ *Id.* at 8727–28.

⁷⁴ *Id.* at 8728.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.* at 8729.

⁷⁹ *Id.*

⁸⁰ *Id.* For additional discussion regarding the Departments' consideration of the First Amendment and RFRA, see *infra* Part III.

6. The February and August 2012 Guidance

HHS issued a guidance document regarding the one-year enforcement safe harbor for non-exempted, non-grandfathered group health plans established and maintained by nonprofit organizations with religious objections to contraceptive coverage. The guidance was first issued on February 10, 2012, and then with minor clarifying amendments on August 15, 2012.⁸¹ The safe harbor was available only to a defined set of organizations: nonprofit organizations whose plans had consistently not covered all or the same subset of contraceptive services for religious reasons at any point from the February 10, 2012 issuance of the guidance onward.⁸² The guidance document specified the criteria that employers, plans, and issuers had to meet to qualify for the safe harbor and, thereby, avoid for one year an enforcement action for failing to cover some or all of the mandated services.⁸³ To qualify for the safe harbor, the organization was required to execute a certification document, and the plan was required to provide participants a specified notice stating that some, or all, contraceptive coverage would not be provided under the plan for the first plan year beginning on or after August 1, 2012.⁸⁴

7. The March 2012 Advance Notice of Proposed Rulemaking (ANPRM)

In March 2012, the Departments issued an advance notice of proposed rulemaking (ANPRM).⁸⁵ The Departments announced an intention to amend regulations regarding certain preventive health services and to establish alternative ways of ensuring preventive health services coverage “when health coverage is sponsored or arranged by a religious organization that objects to the coverage of contraceptive services for religious reasons” but does not qualify for the religious-employer exemption.⁸⁶ The Departments provided for a ninety-day comment period.⁸⁷

The Departments indicated that the ANPRM was “the first step” toward promulgating amended final rules before the end of the temporary enforcement safe harbor so that any accommodation of religious objections by non-exempt, nonprofit religious organizations would be in place at that time.⁸⁸ The ANPRM made it clear

⁸¹ See Ctr. for Consumer Info. & Ins. Oversight (CCIIO), Ctrs. for Medicare & Medicaid Servs. (CMS), *Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code*, CMS.GOV (Feb. 10, 2012), available at http://www.nacua.org/documents/HHS_HealthInsurance_Guidance.pdf.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ See Certain Preventive Services Under the Affordable Care Act, 77 Fed. Reg. 16,501 (Mar. 21, 2012) [hereinafter *Advance Notice*]; Student Health Insurance Coverage, 77 Fed. Reg. 16,453, 16,456–57 (Mar. 21, 2012).

⁸⁶ *Advance Notice*, *supra* note 85, at 16,501.

⁸⁷ *Id.*

⁸⁸ *Id.* at 16,503.

that the Departments had no intention of retreating from their mandate to cover all “[FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.”⁸⁹ The Departments used the ANPRM as a means of presenting “questions and ideas to help shape” discussions with interested persons and stakeholders and to provide “an early opportunity for any interested stakeholder to provide advice and input into the policy development related to the accommodation to be made.”⁹⁰ Among the larger questions posed were: (1) Who qualifies for the accommodation?⁹¹ and (2) Who administers the accommodation?⁹² Under each of these larger questions were a host of sub-issues that required the Departments to gather information, as well as other questions related to such matters as religious health insurance issuers or third-party administrators.⁹³ The Departments emphasized that they wanted to hear from “all points of view on how to provide women access to the important preventive services at issue without cost sharing while accommodating religious liberty interests.”⁹⁴

In the ANPRM, the Departments stated that, “[o]n February 10, 2012, [they made a] commit[ment] to working with stakeholders to develop alternative ways of providing contraceptive coverage without cost sharing in order to accommodate non-exempt, non-profit religious organizations with religious objections to such coverage.”⁹⁵ The Departments indicated that, since the February 2012 announcement, they had met with representatives of various groups and stakeholders to identify issues related to the accommodation.⁹⁶ These consultations, in the Departments’ words, “*began to provide* more detailed information on how health coverage arrangements are currently structured, how religious accommodations work in States with contraceptive coverage requirements, and the landscape with respect to religious organizations that offer health benefits today.”⁹⁷ They also gave the following explanation for the extended comment period:

The 90-day comment period is designed to encourage maximum input into the development of an accommodation for religious organizations with religious objections to providing contraceptive coverage while ensuring the availability of contraceptive coverage without cost sharing for plan participants and beneficiaries. The Departments seek comments on the ideas and questions outlined in this ANPRM as well as new suggestions to achieve its goals. The Departments also intend to hold listening sessions to ensure all voices are heard. This will not be the only opportunity for comment. The subsequent notice of proposed rulemaking

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.* at 16,504–05.

⁹² *Id.* at 16,505–07.

⁹³ *Id.* at 16,504–08.

⁹⁴ *Id.* at 16,503.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* (emphasis added).

will also include a public comment period. The Departments aim to ensure that the final accommodation is fully vetted and published in advance of the expiration of the temporary enforcement safe harbor.⁹⁸

8. The February 2013 Proposed Rulemaking

In February 2013, the Departments issued proposed amendments to the rules regarding coverage of certain preventive services.⁹⁹ Unlike the method of rulemaking used earlier to determine the coverage of preventive services and contraceptive services,¹⁰⁰ the Departments this time used the standard notice-and-comment rulemaking process: They provided notice, requested comments from interested persons on the proposed rules, set aside sixty days for the public to participate meaningfully, and allowed time for the Departments to review and evaluate the comments before finalizing and putting the rules into effect.¹⁰¹

In the regulatory materials, the Departments acknowledged receiving approximately 200,000 comments from a variety of stakeholders in response to the ANPRM.¹⁰² The commenters provided feedback regarding the religious-employer exemption, the proposed accommodation, and other questions and issues raised by the Departments.¹⁰³ As to the religious-employer exemption, some commenters expressed concern that the exemption was too narrow, and others argued that the exemption should be broadened to bring it into alignment with conscience clauses and exemptions in other federal laws and to avoid issues under the First Amendment and RFRA.¹⁰⁴ Other commenters stated that the exemption should not be broadened, arguing that the mandate did not infringe on rights protected by the First Amendment or RFRA.¹⁰⁵ As to the accommodation, some commenters argued that it failed to accommodate religious objections adequately and that, even with the accommodation, plan sponsors would end up funding the coverage.¹⁰⁶ Others argued that the Departments should expand the accommodation to encompass a larger set of organizations that object on moral or religious grounds, and some suggested criteria used in other federal laws.¹⁰⁷ Some commenters advocated for a narrow

⁹⁸ *Id.* at 16,508.

⁹⁹ *See* Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 8456 (Feb. 6, 2013) [hereinafter *Proposed Rules*].

¹⁰⁰ *See supra* Parts II.B.1, II.B.4–5.

¹⁰¹ *See Proposed Rules, supra* note 99, at 8457. Comments were due on or before April 8, 2013.

¹⁰² *Id.* at 8459.

¹⁰³ *Id.* at 8459–60.

¹⁰⁴ *Id.* at 8459.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* Some commenters urged the Departments to rescind the mandate, provide an exemption to any organization that objected to contraceptive services on religious or moral grounds, or provide government funding for the contraceptive services. *Id.*

¹⁰⁷ *Id.* at 8459–460.

accommodation, arguing that the Departments should not expand the accommodation to other types of organizations.¹⁰⁸

The Departments proposed amending the existing rules in two respects. First, the proposed rules would amend the authorization granted to HRSA to exempt group health plans that are established or maintained by certain religious employers with respect to the requirement to cover contraceptive services.¹⁰⁹ This first modification would adjust the qualifying criteria for the religious-employer exemption.¹¹⁰ Accordingly, the Departments proposed eliminating the first three criteria from the existing rules and retaining the fourth as the definition of religious employer.¹¹¹ In the Departments' view, this approach would avoid inquiry into the purposes and the religious beliefs of employers and employees and limit the scope of the exemption to churches, synagogues, mosques, other houses of worship, and religious orders as the Departments' exemption contemplated when the final rules were issued in 2012.¹¹²

Second, the Departments would provide accommodations to group health plans established or maintained by eligible organizations, including student health insurance coverage arranged by eligible religious institutions of higher education.¹¹³ In proposing the accommodations, the Departments specified criteria for determining the eligibility of organizations and a process for organizations to self-certify their qualification for an accommodation.¹¹⁴ In order to ensure that women would receive contraceptive coverage without cost sharing, the Departments proposed means by which participants and beneficiaries would be enrolled and provided coverage by health insurance issuers independent of the objecting organizations.¹¹⁵ The Departments' goal for the proposed rules was to safeguard coverage while protecting "eligible organizations from having to contract, arrange, pay or refer for contraceptive coverage to which they object on religious grounds."¹¹⁶

9. The July 2013 Final Rulemaking

In July 2013, the Departments issued their final rules regarding coverage of certain preventive services.¹¹⁷ These rules went into effect on August 1, 2013, and they applied to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014.¹¹⁸ The amendments to the religious-employer exemption applied to plans and issuers beginning on or after August 1, 2013.¹¹⁹

¹⁰⁸ *Id.* at 8460.

¹⁰⁹ *Id.* at 8456–457, 8460.

¹¹⁰ *See id.* at 8459–460.

¹¹¹ *Id.* at 8461.

¹¹² *Id.*

¹¹³ *Id.* at 8457–460.

¹¹⁴ *Id.* at 8462.

¹¹⁵ *Id.* at 8462–464.

¹¹⁶ *Id.* at 8462.

¹¹⁷ *July 2013 Final Rules*, *supra* note 17, at 39,870.

¹¹⁸ *Id.* at 39,871.

¹¹⁹ *Id.* at 39,874.

The Departments reported receiving over 400,000 comments in response to the proposed rules, and they indicated that they considered these comments before issuing the final rules.¹²⁰ Some of the arguments advanced by commentators were that contraceptive services do not prevent disease, that some are harmful to women, and that they should not be considered preventive health services.¹²¹ The Departments responded that the HRSA guidelines “are based on recommendations of the independent [IOM Committee], which undertook a review of the scientific and medical evidence on women’s preventive services.”¹²² The Departments reiterated some of the same reasons identified in the regulatory materials accompanying their February 2012 final rules, but this time they added that contraceptives, by reducing the number of unintended pregnancies, would reduce the number of women seeking abortions.¹²³ The Departments also responded to a wide range of comments regarding the religious-employer exemption and the accommodations.¹²⁴

In the regulatory materials accompanying these final rules, the Departments gave RFRA and the First Amendment more substantial consideration than in prior rulemakings.¹²⁵ Their consideration, however, extended only to matters involving religious employers and certain non-exempt, nonprofit religious organizations.¹²⁶ The Departments expressed their view that the accommodations do not violate RFRA and that the religious-employer exemption and accommodations violate neither the Establishment Clause nor the Free Exercise Clause of the First Amendment.¹²⁷ Finally, they asserted that the FDA-approved contraceptive methods, which include Plan B, Ella, and IUDs, are not abortifacient within the meaning of federal law and do not violate federal restrictions relating to abortion.¹²⁸

In these final rules, the Administration completed its rulemaking on the mandate, finalizing the rules on two remaining issues.¹²⁹ First, the Administration modified the religious-employer definition for purposes of the exemption.¹³⁰ Under the final rules, a “religious employer” is “an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.”¹³¹

Second, the Administration provided accommodations for group health plans that are established or maintained by eligible nonprofit religious organizations and for

¹²⁰ *Id.* at 39,871.

¹²¹ *Id.* at 39,872.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.* at 39,873–88.

¹²⁵ *Id.* at 39,886–88.

¹²⁶ *Id.* at 39,886–88.

¹²⁷ *Id.* at 39,888.

¹²⁸ *Id.*

¹²⁹ *Id.* at 39,870, 73.

¹³⁰ *Id.* at 39,873–74.

¹³¹ *Id.* at 39,886.

student health insurance coverage arranged by eligible organizations that are institutions of higher education.¹³² Under the final rules, an organization has to meet the following criteria to be eligible for an accommodation:

- (1) It has to oppose providing coverage for some or all of the mandated contraceptive services on account of religious objections;
- (2) It has to be organized and operate as a nonprofit entity;
- (3) It has to hold itself out as a religious organization; and
- (4) It has to self-certify (on a specified form) that it satisfies the first three requirements.¹³³

The rules also impose specific requirements on insurance issuers that have received a self-certification from an eligible organization.¹³⁴ They must expressly exclude contraceptive coverage from the group plan coverage and provide separate payments for any services that coverage is required for.¹³⁵ Additionally, they must segregate premium revenue collected from an eligible organization from monies used to provide payment for contraceptive services, and they must provide notice to participants and beneficiaries of the availability of separate coverage.¹³⁶

10. The June 2013 Guidance Documents

In June 2013, contemporaneous with the issuance of the final rules, the Administration issued two additional guidance documents. The first document extended the temporary enforcement safe harbor to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014.¹³⁷ The second was a self-certification form for organizations seeking an accommodation under the final rules to execute.¹³⁸

C. Some Observations Regarding the Processes Used to Develop the Mandate

As the preceding review of the regulatory actions that implemented the mandate shows, the important policy decision to include contraceptive methods, sterilization procedures, and patient education and counseling within the preventive health services that must be covered without cost sharing was not made by the duly-elected

¹³² *Id.* at 39,873–82.

¹³³ *Id.* at 39,892.

¹³⁴ *Id.* at 39,893, 39,895–96.

¹³⁵ *Id.*

¹³⁶ *Id.* at 39,893, 39,895–97.

¹³⁷ Ctr. for Consumer Info. & Ins. Oversight (CCIIO), Ctrs. for Medicare & Medicaid Servs. (CMS), *Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code*, CMS.GOV (June 28, 2013), <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf>.

¹³⁸ Ctr. for Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Servs., *Self Certification Form*, CMS.GOV (June 28, 2013), <http://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/index.html#Prevention>.

representatives of the American people serving in the U.S. Congress. In the ACA, Congress had not defined what would be included within the coverage package of preventive health services for women. Instead, it gave that decision-making responsibility to the executive branch, and consequently the decision was made by individuals within the Administration.

The Departments chose to use truncated administrative rulemaking procedures to promulgate the mandate. By using the interim final rulemaking process, the Administration hindered meaningful public participation, hampered dialogue between policymakers and interested individuals and organizations, and prevented full vetting of the rules before they went into effect. In other words, the regulatory procedures chosen by the Administration thwarted what is supposed to be a transparent, deliberative rulemaking process in which the public has the opportunity to participate meaningfully. Consequently, the public's interest in meaningful participation in administrative rulemaking and its interest in transparent, deliberative policy decision-making were not well served by the processes employed by the Administration to develop and impose the mandate.

In the February/March 2012 timeframe, the Administration appeared to shift its approach to rulemaking regarding the mandate.¹³⁹ In the March 2012 ANPRM, the Departments stated that they committed on *February 10, 2012* (when they issued the "final-final rules" approving the amended interim final rules, the mandate, and the narrow religious-employer exemption) to working with stakeholders to ensure the provision of contraceptive coverage without cost sharing while accommodating certain nonprofit religious organizations that were opposed to providing the mandated coverage on religious grounds. That shift is also signaled by the Departments' transition from using interim final rulemaking to the regular notice-and-comment rulemaking process and their explanation of why they were issuing an ANPRM and providing for an extended comment period and listening sessions before issuing a subsequent proposed rulemaking and providing an additional opportunity to comment. In other words, from the February/March 2012 timeframe forward, the Departments manifested a willingness to permit meaningful public participation in rulemaking and the full vetting of the rules. However, at that point, the Department had already developed and promulgated the mandate. The only remaining issues were how narrow the religious-employer exemption would be, what sort of accommodations would be extended to certain non-exempt, nonprofit religious organizations, and how the accommodations would be administered.

A review of the Departments' rulemaking activities shows that, once the Administration had succeeded in establishing the mandate and thereby accomplishing its key social and political objectives, it slowed the rulemaking process down and began to employ standard procedures to allow public participation in decisions regarding the scope of the religious-employer exemption and the accommodation for nonprofit, religious organizations. In other words, when the Administration turned its attention to accommodating religious beliefs and conscience objections, it decided to take its time and give the public (including those opposed to a religious-employer exemption and any accommodation of nonprofit

¹³⁹ The year 2012 was a presidential election year, and the contraceptive coverage mandate had become a contentious issue. See Devin Dwyer, *Poll: Americans Divided over Contraception Mandate*, ABC NEWS (Feb. 14, 2012, 4:30 PM), <http://abcnews.go.com/blogs/politics/2012/02/poll-americans-divided-over-contraception-mandate/>.

institutions) a full opportunity to comment on agency proposals. Considering that 2012 was an election year, the shift would allow the Administration to employ the rhetoric of accommodation and public participation and to trumpet its work with stakeholders, the listening sessions, and the full vetting of its rules.

The United States Supreme Court's determination that the Administration's mandate violates the RFRA was issued after the promulgation of rules and actions studied here, and its decision has necessitated additional rulemaking by the Departments.¹⁴⁰ Accordingly, on August 27, 2014, four years after they issued their first set of interim final rules, the Departments issued more rules related to the mandate.¹⁴¹ The Departments issued their new rules for nonprofit organizations as interim final rules, setting the effective date as August 27, 2014, and requiring that comments be received by October 27, 2014.¹⁴² They issued their new rules for for-profit organizations as proposed rules, and they specified that comments must be received on or before October 21, 2014, to be considered.¹⁴³

III. ANALYSIS UNDER THE RELIGIOUS FREEDOM RESTORATION ACT

In promulgating the mandate, the Departments undertook to create a "positive right" or entitlement to coverage of all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling.¹⁴⁴ In creating this

¹⁴⁰ See *infra* Part III.

¹⁴¹ See Coverage of Certain Preventive Services Under the Affordable Care Act, 79 Fed. Reg. 51,092 (Aug. 27, 2014) [hereinafter *August 2014 Interim Final Rules*]; 79 Fed. Reg. 51,118 [hereinafter *August 2014 Proposed Rules*]. An analysis of these new rules would extend this Article beyond the scope of the study undertaken here, which has focused on the rules up to their final form in July 2013. Additionally, these new rules were issued as this Article was being finalized for publication.

¹⁴² *August 2014 Interim Final Rules*, *supra* note 141, at 51,092.

¹⁴³ *August 2014 Proposed Rules*, *supra* note 141, at 51,119.

¹⁴⁴ *Id.* at 51,121. Philosopher Isaiah Berlin is typically credited with recognizing the basic distinction between negative rights or liberties and positive rights or liberties. See Isaiah Berlin, *Two Concepts of Liberty*, in *FOUR ESSAYS ON LIBERTY* 118 (1969). As conventionally understood, the concept of negative rights entails freedom or protection from government action or interference (e.g., the freedom of religion and speech), and the concept of positive rights entails entitlement to government action or support (e.g., the right to education). See Susan Bandes, *The Negative Constitution: A Critique*, 88 MICH. L. REV. 2271, 2272 (1990) ("No inquiry is more central to constitutional jurisprudence than the effort to delineate the duties of government. The courts' approach to this complex subject has been dominated by reliance on a simple distinction between affirmative and negative responsibilities. Government is held solely to what courts characterize as a negative obligation: to refrain from acts that deprive citizens of protected rights. Obligations that courts conceive to be affirmative—duties to act, to provide, or to protect—are not enforceable constitutional rights."); Mark Tushnet, *An Essay on Rights*, 62 TEX. L. REV. 1363, 1364, 1392 (1984) ("Part of the conventional wisdom about rights distinguishes between negative rights—to be free from interference—and positive rights to have various things. People sympathetic to the party of humanity [(i.e., 'progressive social forces')] usually agree that the present balance between negative and positive rights is askew and that we should strengthen or create positive rights while preserving most of our negative rights. Yet, viewed pragmatically, it may be impossible to carry out that program. In our culture, the image of negative rights overshadows that of positive ones and may obstruct the expansion of positive rights."). Courts have also recognized this distinction. See DeShaney

positive right, however, the federal government did not assume the affirmative responsibility of providing or paying for the coverage. Rather, under the ACA and the Administration's rules, the federal government required group health plans, health insurance issuers, and employers to take action or provide support by making them responsible for providing services prescribed by a health care provider and used by the patient.¹⁴⁵ In other words, the Administration made third parties to health care provider-patient relationships responsible for the entitlement of patients by requiring them to pay for the services.¹⁴⁶

More than 300 individuals and entities filed over 100 cases challenging the mandate and the burden the Administration placed upon them to pay for these services.¹⁴⁷ Almost an equal number of cases have been brought by for-profit organizations as by nonprofit organizations.¹⁴⁸ In these challenges, the litigants have argued that they are opposed on religious and moral grounds to the federal government requiring them to pay for certain specified services to which they object on religious and moral grounds.¹⁴⁹ Among the principal claims alleged by the plaintiffs in these cases are claims under the First Amendment and RFRA.¹⁵⁰

These challenges focus attention on the conflict the Administration precipitated between the positive right to contraceptive coverage created by its regulatory rule and the negative right of religious freedom recognized in the First Amendment and reinforced in RFRA, which afford protection from government interference.¹⁵¹ As the discussion above and below shows, the Departments failed to consider the First Amendment and RFRA until after they had developed and imposed the mandate, and when they did finally consider the First Amendment and RFRA, it was only in the context of their narrow religious-employer exemption and their narrow accommodations for certain non-exempt, nonprofit religious organizations with religious objections to paying for the services.¹⁵² The Administration's failure to consider the application of the First Amendment and RFRA left the mandate

v. Winnebago County Dep't of Soc. Servs., 489 U.S. 189, 195–96 (1989); *id.* at 204 (Brennan, J., dissenting); *Slade v. Bd. of Sch. Dir. of City of Milwaukee*, 702 F.3d 1027, 1031 (7th Cir. 2012).

¹⁴⁵ See *August 2014 Proposed Rules*, *supra* note 141, at 51,122. For a discussion of the statutory and regulatory developments that led to the mandate, see *infra* Part II.

¹⁴⁶ The third-party payment structure is an established part of health care financing in the United States. See Thomas Bodenheimer & Kevin Grumbach, *Paying for Health Care*, 272 JAMA 634 (Aug. 24, 1994).

¹⁴⁷ See *HHS Mandate Information Central*, THE BECKET FUND, <http://www.becketfund.org/hhsinformationcentral> (last visited Nov. 8, 2014).

¹⁴⁸ See *id.*

¹⁴⁹ See, e.g., *Eternal World Television Network, Inc. v. Burwell*, 756 F.3d 1339, 1348 (11th Cir. 2014); *Nebraska ex rel. Bruning v. Sebelius*, 877 F.Supp. 2d 777, 788 (D. Neb. 2012).

¹⁵⁰ *Eternal World Television Network*, 756 F.3d at 1348 (“The Network alleged that the mandate violated the Religious Freedom Restoration Act, the First Amendment, the Fifth Amendment, and the Administrative Procedure Act.”); *Sebelius*, 877 F.Supp. 2d at 788 (alleging violations of the First Amendment and RFRA).

¹⁵¹ See *supra* note 144 and sources cited therein.

¹⁵² See *supra* Part II.B; *infra* Part III.A.

vulnerable to challenge, and the RFRA claim ultimately succeeded because Congress, in RFRA, had required the federal government to meet a high standard to justify burdens it places on the negative right of religious freedom.¹⁵³

The RFRA analysis performed here proceeds by first evaluating the Departments' consideration of (and failure to consider) RFRA in their rulemakings. It then outlines the test established by Congress in RFRA and studies the Supreme Court's recent ruling that the mandate violates RFRA. The analysis concludes with a brief, selective survey of other challenges to the mandate.

A. *The Departments' Rulemakings*

During the course of their rulemakings, the Departments failed to give adequate consideration to religious freedom and the requirements of the First Amendment and RFRA. The Departments did not consider the First Amendment or RFRA at any point in the interim final rules or in the regulatory materials accompanying the rules issued in July 2010.¹⁵⁴ Likewise, the Departments considered neither the First Amendment nor RFRA at any point in the amended interim final rules or in the regulatory materials accompanying the rules issued in August 2011.¹⁵⁵

By the time of the August 2011 rulemaking, the Administration's mandate that group health plans, health insurance issuers, and many employers cover all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling was approved and in place.¹⁵⁶ In that rulemaking, the Departments indicated that they had received comments from the public and interested persons as to their July 2010 interim final rules that raised concerns regarding religious institutions, and in response to those comments, they authorized HRSA to establish a religious-employer exemption and promulgated a definition of religious employers that governed the scope of that exemption.¹⁵⁷ And, yet, despite their acknowledged awareness that their rules raised concerns for religious institutions, the Departments did not analyze their regulatory action under the First Amendment or RFRA or evaluate how the First Amendment or RFRA applied to their actions and the burdens they were imposing on any nonprofit organizations, religious institutions, or for-profit organizations.

The Departments first considered the potential application of the First Amendment and RFRA in February 2012 when they adopted their July 2010 interim final rules and August 2011 amended interim final rules as final rules without change.¹⁵⁸ In those final-final rules, the Departments announced the one-year

¹⁵³ See *infra* Part III.B.

¹⁵⁴ See *supra* Part II.B.1. Considering Planned Parenthood's contemporaneous announcement of its campaign to include all-FDA approved contraceptives in HRSA's *Women's Preventive Services Guidelines* and HHS's representation that these guidelines were already in development, the Departments cannot reasonably argue that the controversy surrounding the mandate was not foreseeable. See Part II.B.1.

¹⁵⁵ See *supra* Part II.B.4.

¹⁵⁶ See *supra* Parts II.B.2–4. Additionally, neither the Committee that recommended coverage of these services nor HRSA that issued the *Women's Preventive Services Guidelines* considered the application of the First Amendment and RFRA.

¹⁵⁷ See *supra* Part II.B.4.

¹⁵⁸ See *supra* Part II.B.5.

enforcement safe harbor for certain non-exempt, nonprofit religious organizations with religious objections, and their plan to develop accommodations for such organizations.¹⁵⁹ Their consideration of the First Amendment and RFRA was, however, limited in scope, focusing on their approach of providing a narrow religious-employer exemption, creating the temporary enforcement safe harbor, and developing some narrowly defined accommodations.¹⁶⁰

Furthermore, although the Departments considered the First Amendment and RFRA in their February 2012 rulemaking, their consideration was superficial and conclusory.¹⁶¹ As to the First Amendment, the Departments asserted that the mandate was “generally applicable and designed to serve the compelling public health and gender equity goals described” in the regulatory materials and that the mandate “is in no way specifically targeted at religion or religious practices.”¹⁶² The Departments’ consideration of RFRA was even more cursory: “[the Departments’] approach complies with [RFRA], which generally requires a federal law to not substantially burden religious exercise, or, if it does substantially burden religious exercise, to be the least restrictive means to further a compelling government interest.”¹⁶³ In the regulatory materials accompanying their final-final rules, the Departments provided no further discussion of the constitutional and statutory standards or contemplated any alternative means of promoting their stated interests.¹⁶⁴

In their July 2013 rulemaking, nearly two full years after the mandate was firmly in place, the Departments finally gave something more than passing consideration to some religious freedom issues created by the mandate.¹⁶⁵ In that nearly two-year period, commenters on the rules had raised concerns regarding religious freedom, conscience, and moral objections to abortion and contraceptives.¹⁶⁶ Additionally, litigation had been instituted as early as November and December 2011,¹⁶⁷ just a few months after the contraceptive mandate was in place in August 2011, and those cases presented claims under the First Amendment and RFRA.¹⁶⁸ Both Planned Parenthood and the USCCB had publicly expressed opposing views on the mandate and communicated with the Administration.¹⁶⁹ Furthermore, the HHS-funded IOM

¹⁵⁹ See *supra* Part II.B.5.

¹⁶⁰ See *supra* Part II.B.5.

¹⁶¹ See *supra* Part II.B.5.

¹⁶² See *Final Rules*, *supra* note 59, at 8729. In this same paragraph, the Departments recited aspects of the applicable constitutional standard: “The Supreme Court has held that the First Amendment right to free exercise of religion is not violated by a law that is not specifically targeted at religiously motivated conduct and that applies equally to conduct without regard to whether it is religiously motivated—a so-called neutral law of general applicability.” *Id.*

¹⁶³ *Id.*

¹⁶⁴ See *id.* at 8725–30.

¹⁶⁵ See *supra* Part II.B.9.

¹⁶⁶ See *Amended Interim Final Rules*, *supra* note 43, at 46,623–24; *Final Rules*, *supra* note 59, at 8726–27; *July 2013 Final Rules*, *supra* note 17, at 39,886–88.

¹⁶⁷ See *supra* note 62 and sources cited therein.

¹⁶⁸ *Id.*

¹⁶⁹ See *supra* notes 2728–29 and accompanying text.

Committee had given representatives of such groups as Planned Parenthood, the Guttmacher Institute, and the National Women's Law Center opportunity to shape the views of Committee members on the issues, influence the development of its recommendation, and help build "the record" that the Departments would rely on in their rulemaking.¹⁷⁰

In the July 2013 rulemaking, the Departments' consideration of the First Amendment and RFRA was focused on the exemption and the proposed accommodations.¹⁷¹ In the regulatory materials, the Departments expressed their belief that the exemption and the accommodations did not violate the Establishment Clause because they were available on an equal basis to any and all religions.¹⁷² Likewise, in their view, the exemption and the accommodations did not violate the Free Exercise Clause because they were neutral and generally applicable, did not target religiously motivated conduct, and served to accommodate religion, not to disfavor it.¹⁷³

As to RFRA, the Departments expressed their view that accommodations were not required by RFRA.¹⁷⁴ Additionally, in their view, "the accommodations" did not violate RFRA for several reasons: (1) they did not substantially burden religious exercise; (2) they served two compelling government interests, namely, safeguarding public health by expanding access to and utilization of recommended preventive services, and ensuring that women have equal access to health care services; and (3) they were the least restrictive means to achieve those interests.¹⁷⁵ The Departments disagreed with commenters who expressed concern that, even with the accommodations, their organizations were required to be involved in providing coverage of objectionable services, to provide the self-certification, and to fund or subsidize coverage, and they disputed the claims of commenters who argued that alternative means were available.¹⁷⁶

At no point in these rulemakings did the Departments evaluate the application of the First Amendment or RFRA to the burdens the mandate imposed on the religious freedom and consciences of for-profit organizations and the individuals who own them. Similarly, at no point in these rulemakings did the Department consider carefully under RFRA questions regarding the scope of the religious-employer exemption. Furthermore, as shown above, what consideration the Departments did give to religious freedom and moral objections to the mandate was late and insufficient to address those concerns meaningfully.

B. The RFRA Standard

During the period when the Departments were developing and finalizing the mandate, RFRA provided one of the primary standards for evaluating whether and

¹⁷⁰ See *supra* Part II.B.2.

¹⁷¹ See *July 2013 Final Rules*, *supra* note 17, at 39,886–88.

¹⁷² See *id.* at 39,888.

¹⁷³ *Id.*

¹⁷⁴ *Id.* at 39,886.

¹⁷⁵ *Id.* at 39,886–87.

¹⁷⁶ See *id.* at 39,887–88.

under what circumstances the federal government may impose a specific burden on religious freedom. In 1993, Congress passed RFRA, and President Clinton signed it into law.¹⁷⁷ In passing this legislation, Congress acted with virtual unanimity in response to the Supreme Court's ruling in *Employment Division v. Smith*.¹⁷⁸ In *Smith*, the Court had held that, under the First Amendment, neutral, generally applicable laws may be applied to religious practices even when not supported by a compelling governmental interest.¹⁷⁹

In RFRA, Congress mandated broad protection for religious liberty, and this is reflected in the legislative findings. Congress found that the free exercise of religion is an unalienable right protected in the First Amendment and that religious exercise is burdened by "laws 'neutral' toward religion . . . as surely as laws intended to interfere with religious exercise."¹⁸⁰ According to Congress, the government must have a compelling interest to substantially burden religious exercise, and the Court in *Smith* had "virtually eliminated the requirement that the government [must] justify burdens on religious exercise imposed by laws neutral toward religion."¹⁸¹ Congress deemed the compelling interest standard "a workable test" for striking "sensible balances" between religious liberty and governmental interests.¹⁸² In enacting RFRA, Congress was motivated by two purposes: (1) restoring the compelling interest test that the Court approved in *Sherbert v. Verner* and *Wisconsin v. Yoder*, and requiring its application in all cases where the free exercise of religion is substantially burdened; and (2) providing a claim or defense to persons whose religious exercise is substantially burdened by government.¹⁸³

Accordingly, under RFRA, the federal government may "not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability," except when it meets two requirements.¹⁸⁴ When the government's action substantially burdens religious exercise, it must demonstrate that the burden (1) promotes a compelling governmental interest and (2) is the least restrictive means of furthering that interest.¹⁸⁵ RFRA defines "exercise of religion" and "religious exercise" broadly to include "any exercise of religion whether or not compelled by, or central to, a system of religious belief."¹⁸⁶

¹⁷⁷ Religious Freedom Restoration Act of 1993, 107 Stat. 1488, 42 U.S.C. § 2000bb *et seq.*

¹⁷⁸ *See Emp. Div., Dep't of Human Res. of Ore. v. Smith*, 494 U.S. 872 (1990).

¹⁷⁹ *See id.* at 877–90. *See also* *City of Boerne v. Flores*, 521 U.S. 507, 514 (1997) (discussing *Smith*)

¹⁸⁰ 42 U.S.C. § 2000bb(a) (2012).

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ 42 U.S.C. § 2000bb(b) (2012) (citing *Sherbert v. Verner*, 374 U.S. 398 (1963); *Wisconsin v. Yoder*, 406 U.S. 205 (1972)).

¹⁸⁴ *Id.* § 2000bb-1(a).

¹⁸⁵ *Id.* § 2000bb-1(b).

¹⁸⁶ *Id.* §§ 2000bb-2(4), 2000cc-5(7)(A)

Under RFRA, a person whose religious exercise is burdened may bring a claim asserting a violation of RFRA and obtain appropriate relief.¹⁸⁷ The religious claimant must establish a prima facie case by showing the following: (1) a burdened practice is an exercise of religion; (2) the burdened religious practice is sincere; and (3) the burden is substantial.¹⁸⁸ The federal government then carries the burden of proof and must demonstrate that its application of the law (1) is in furtherance of a compelling governmental interest and (2) is the least restrictive means of achieving that interest.¹⁸⁹

As noted earlier, the Departments did not consider the application of this standard to their mandate in the July 2010 rulemaking or the August 2011 rulemaking.¹⁹⁰ Even in the February 2012 rulemaking, when they finalized without any change their interim final rules, they did not apply this standard—they merely recited it.¹⁹¹ The Departments did not apply this standard to the mandate until the July 2013 rulemaking when they completed their rulemaking on the mandate; but, even then, the Departments' consideration of the standard was focused on the accommodations.¹⁹² At no point during the three-year history of their rulemakings on the mandate did the Departments consider the application of this standard to their requirement that for-profit organizations provide the mandated coverage.¹⁹³ Thus, the for-profit litigants who challenged the mandate and the courts that heard those challenges performed an analysis under RFRA that the Departments themselves had failed to perform in their rulemakings.¹⁹⁴

C. The Supreme Court's Ruling

On June 30, 2014, the Supreme Court issued its ruling holding that the Administration's mandate violated RFRA.¹⁹⁵ The specific question decided by the

¹⁸⁷ *Id.* § 2000bb-1(c). Under RFRA, standing is determined “by the general rules of standing under article III of the Constitution.” *Id.*

¹⁸⁸ *Cf.* *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 428 (2006).

¹⁸⁹ 42 U.S.C. § 2000bb-1(b). Under RFRA, “demonstrates” means “meets the burdens of going forward with the evidence and of persuasion.” *See* 42 U.S.C. § 2000bb-2(3) (2000).

¹⁹⁰ *See supra* Part III.A.

¹⁹¹ *See supra* Parts II.B.5, III.A.

¹⁹² *See supra* Part III.A.

¹⁹³ For a more extensive review of this rulemaking making history, *see supra* Parts II.B, III.A.

¹⁹⁴ Even if the Departments believed that for-profit entities are not persons under RFRA, the RFRA analysis would still be warranted to give the public a rational explanation for their decisions in the rulemaking. More importantly, the question whether for-profit entities are persons under RFRA was at least a debatable issue, and the Departments were not warranted in assuming they were not.

¹⁹⁵ *Burwell v. Hobby Lobby Stores, Inc.*, 134 S.Ct. 2751, 2758 (2014), *aff'g* *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013), and *rev'g and remanding* *Conestoga Wood Specialties Corp. v. Sebelius*, 724 F.3d 377 (3d Cir. 2013). Justice Kennedy concurred in the Court's opinion, but wrote a separate concurring opinion. He emphasized that the Court's opinion is premised upon “its assumption” that the government has “a legitimate and

Court was whether RFRA permits HHS “to demand that three closely held corporations provide health-insurance coverage for methods of contraception that violate the sincerely held religious beliefs of the companies’ owners.”¹⁹⁶

The Court determined that for-profit corporations (and individuals like the Greens and the Hahns who own and control them) are persons under RFRA and that protecting the religious freedom of corporations protects the religious freedom of the individuals who own and control them.¹⁹⁷ According to the Court, in RFRA, Congress did not discriminate against owners of companies who desire to operate their businesses in a manner required by their religious beliefs when they decide to organize their businesses as corporations, as opposed to sole proprietorships or general partnerships.¹⁹⁸ Accordingly, federal regulations that restrict the activities of for-profit closely-held corporations must conform to the requirements of RFRA.¹⁹⁹

As to the *prima facie* case that the companies had to show, the Court determined that the mandate substantially burdens religious exercise.²⁰⁰ The Court explained that the Greens and the Hahns sincerely believe that life begins at conception, that they object to providing health insurance that covers methods that may result in the destruction of an embryo, and that the mandate requires them to “engage in conduct that seriously violates their religious beliefs.”²⁰¹ Finally, if the Greens and the Hahns

compelling interest in the health of female employees” but that the government has failed to show that it is using the least restrictive means, especially considering that the government had allowed a seemingly workable accommodation for other organizations that object on religious grounds. *Hobby Lobby Stores*, 134 S.Ct. at 2786. He also observed that the government has available to it the means of reconciling “two priorities”: “no person may be restricted or demeaned by government in exercising his or her religion,” and “that same exercise [may not] unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling.” *Id.* at 2786–87.

Justice Ginsburg dissented and wrote an opinion that Justice Sotomayor joined in its entirety and that Justices Breyer and Kagan joined as to all but Part III-C-1. Justice Ginsburg expressed concern that the Court’s decision was startlingly broad, allowing “commercial enterprises, including corporations, along with partnerships and sole proprietorships, [to] opt out of any law (saving only tax laws) they judge incompatible with their sincerely held religious beliefs.” *Id.* at 2787. In her view, any free exercise claim under the First Amendment is foreclosed by *Employment Division v. Smith* because the mandate applies generally, is aimed at the wellbeing of women, and would at most have an incidental effect on religious exercise. *Id.* at 2790. Additionally, Justice Ginsburg understood the RFRA claim to fail on every element: for-profit corporations do not exercise religion and thus do not qualify as persons under RFRA for purposes of an exemption from the law; the mandate does not substantially burden the religious exercise of the corporations or the families; the government has shown that its interests in public health and the wellbeing of women are compelling; and the government has shown that there is no less restrictive, equally effective means to satisfy the religious objections and carry out the objective in the mandate. *Id.* at 2793–2803.

¹⁹⁶ *Id.* at 2759.

¹⁹⁷ *See id.* at 2767–75.

¹⁹⁸ *See id.* at 2759–60.

¹⁹⁹ *See id.* at 2775.

²⁰⁰ *Id.* at 2775–79.

²⁰¹ *Id.* at 2775.

(and their companies) fail to comply with the government's mandate, the Court observed, they will suffer serious economic consequences from the penalties imposed by the government.²⁰² The Court thus determined that the government's mandate, coupled with its coercive power to enforce the mandate by imposing substantial penalties, substantially burdens religious freedom.

As to the government's showing under RFRA, the Court assumed without deciding that the interest in guaranteeing cost-free access to the four challenged contraceptive methods is compelling, and the Court then turned to the question of the least restrictive means of furthering that interest.²⁰³ The Court observed that the government itself could assume the cost of providing the four objectionable contraceptive methods and that the government had not shown that that alternative was not viable, especially considering that the ACA's insurance-coverage provisions will require the government to assume over \$1.3 trillion in costs over the next decade.²⁰⁴ The Court added: "If, as HHS tells us, providing all women with cost-free access to all FDA-approved methods of contraception is a Government interest of the highest order, it is hard to understand HHS's argument that it cannot be required under RFRA to pay *anything* in order to achieve this important goal."²⁰⁵ But, in the Court's view, it was the Administration's accommodation of nonprofit organizations with religious objections that most clearly demonstrated the availability of a less restrictive alternative.²⁰⁶ Thus, the Court determined that the federal government had failed to carry its burden of showing that the mandate is the least restrictive means of furthering the government's interest. The mandate was found, as a result, to violate RFRA as applied to closely-held corporations.²⁰⁷

D. Other Challenges

In the cases brought by Hobby Lobby Stores and Conestoga Wood Specialties, the Supreme Court determined that the mandate violates RFRA as applied to closely-held for-profit corporations. Dozens of cases filed by nonprofit organizations remain pending.²⁰⁸ In *Wheaton College v. Burwell*, the Court issued an order on the religious nonprofit college's application for injunction pending appeal.²⁰⁹ The Court enjoined the government from enforcing against Wheaton College "the challenged provisions of the [ACA] and related regulations pending final disposition of appellate review," if the college notifies HHS in writing that "it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for

²⁰² See *id.* at 2775–76.

²⁰³ See *id.* at 2779–80.

²⁰⁴ See *id.* at 2780–81 (citing estimates by the Congressional Budget Office).

²⁰⁵ *Id.* at 2781 (emphasis in original).

²⁰⁶ See *id.* at 2781–82.

²⁰⁷ See *id.* at 2785. The Court concluded that it did not need to reach the First Amendment free exercise claim because its decision on the statutory issue resolved the question. *Id.*

²⁰⁸ See *HHS Mandate Information Central*, THE BECKET FUND, <http://www.becketfund.org/hhsinformationcentral/> (last visited Nov. 8, 2014).

²⁰⁹ *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014).

contraceptive services.”²¹⁰ The college objected to providing its health insurance issuer and third-party administrator notice of its objection, which would trigger the obligation of the issuer and administrator to provide coverage.²¹¹ In *Little Sisters of the Poor Home for the Aged v. Sebelius*, the Court had issued a similar order enjoining the federal government from enforcing the mandate, and the Little Sisters had likewise objected to completing the requisite form and sending copies to third-party administrators.²¹²

On August 27, 2014, the Departments issued more interim final rules and proposed rules regarding coverage of certain preventive services under the ACA.²¹³ In the interim final rules, the Departments added to the existing rules based upon the Court’s ruling in the *Wheaton College* case and provided an alternative process for eligible organizations to provide notice of their religious objections to contraceptive coverage.²¹⁴ In the proposed rules, the Departments proposed changing the definition of eligible organization in their rules based upon the Court’s ruling in the *Hobby Lobby Stores* case.²¹⁵

Given the number of pending cases, and the additional rulemakings by the Departments, litigation challenging the mandate is likely to persist for some time. It remains to be seen how the Court’s ruling in the *Hobby Lobby Stores* case will be applied to other for-profit businesses and to the wide range of nonprofit organizations and individuals challenging the mandate.

The mandate’s complicated regulatory history and the three years of litigation challenging the mandate highlight fundamental failures in the Administration’s approach to establishing the mandate through agency rulemaking. The Departments chose to use the interim final rulemaking process that, while accelerating rulemaking, restricted and delayed meaningful participation by the public, including the participation of individuals and organizations adversely affected by the mandate. The Departments’ choice to use this truncated rulemaking process hampered deliberation and deprived them of feedback from the public that would have led to more carefully reasoned rulemakings. Had the Departments chosen to use the standard notice-and-comment rulemaking process, issues under the First Amendment and RFRA would have likely come into focus earlier, and the Departments could have addressed those issues earlier. As it was, the Departments were years behind in performing the statutorily-required analysis under RFRA. Moreover, in their rulemakings, they never performed the RFRA analysis as to the burden their mandate imposed on for-profit organizations. Consequently, the Departments invited trouble by leaving the performance of that analysis to litigants and the courts.

²¹⁰ *Id.* at 2807.

²¹¹ *See id.*

²¹² *See Little Sisters of the Poor Home for the Aged v. Sebelius*, 134 S. Ct. 1022 (2014).

²¹³ *See August 2014 Interim Final Rules*, *supra* note 141; *August 2014 Proposed Rules*, *supra* note 141. *See also supra* Part II.C.

²¹⁴ *See August 2014 Interim Final Rules*, *supra* note 141, at 51,092.

²¹⁵ *See August 2014 Proposed Rules*, *supra* note 141, at 51,118.

IV. ANALYSIS UNDER A PUBLIC HEALTH POLICY AND ETHICS FRAMEWORK

The contraceptive coverage mandate is a public health initiative. Consequently, a public health policy and ethics analysis is warranted. The analysis performed here employs a public health policy and ethics framework proposed by a team of bioethicists and public health law and policy experts. This analysis begins with an overview of that framework and then evaluates the Administration's mandate under the team's proposed analytical structure.

A. *The ACA, the Mandate, Public Health, and Social Justice*

As discussed earlier, Congress in the ACA mandated that group health plans, health insurance issuers, and many employers cover categories of preventive health services with no cost sharing.²¹⁶ In implementing these ACA provisions, the Administration decided to include within the preventive health services coverage package all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling.²¹⁷ In mandating coverage of preventive health services, which now includes contraceptive and sterilization services, Congress and the Administration decided to make use of health plans, health insurance issuers, and employers in the federal government's effort to promote public health.²¹⁸

The decision of Congress and the Administration to cast the mandate in the mold of public health is significant. Health care and medicine are oriented primarily to individuals.²¹⁹ In health care, attention is centered on the physician-patient

²¹⁶ See *supra* Part II.A.

²¹⁷ See *supra* Part II.B.

²¹⁸ See Michael J. DeBoer, *Access Without Limits? Revisiting Barriers and Boundaries After the Affordable Care Act*, 4 CONN. L. REV. 1239, 1257–58 & n.65 (2012). See also John D. Blum, *The Naprapath in the Rainforest*, 18 NEXUS J. L. & PUB. POL'Y 3, 7–8 (2012–2013) (“[T]he ACA contains an array of measures that are directed toward enhancement of preventive and wellness services, and the Act marks a significant and deliberate foray into this traditional area of public health. The efforts undertaken in the ACA concerning prevention and wellness may be cast in a traditional biomedical model, but the efforts are certainly reflective of governmental awareness that broader public health approaches, including information awareness, clinical prevention, and workplace wellness, are critical for health maintenance and potentially play important roles in containing costs of chronic illness.”); John Aloysius Cogan, Jr., *The Affordable Care Act's Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J.L. MED. & ETHICS 355, 355 (2011) (“By requiring . . . health plans to provide evidence-based preventive services with no out-of-pocket costs, the ACA transforms the U.S.'s public and private health care financing systems into vehicles for promoting public health.”); Lorian E. Hardcastle, et al., *Improving the Population's Health: The Affordable Care Act and the Importance of Integration*, 39 J.L. MED. & ETHICS 317, 322 (2011) (discussing insurance reforms in the ACA and major provisions affecting public health and stating that another set of ACA reforms “addresses the demand for public health services by eliminating barriers to preventive services. [Q]ualified health plans can no longer impose costs on patients for services deemed beneficial by the [USPSTF] or for immunizations recommended by the [ACIP]. Preventive care for infants, children, adolescents, and women recommended by the [HRSA] will similarly be free of charge.”).

²¹⁹ See LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 16 (2d ed. 2008).

relationship, and in therapeutic relationships, physicians act in the best interests of their patients, providing care to diagnose and treat injury and illness and to cure disease.²²⁰ By contrast, public health focuses on populations and government efforts to promote the health of populations and to prevent injury, illness, disease, and disability.²²¹ Consequently, in public health, the focus is not on the care of individual patients.²²² Public health has traditionally aimed to promote the common good through government efforts to collect and analyze data and then intervene to prevent and reduce risks and harms.²²³ Traditional public health activities included disease surveillance, sanitation, injury prevention, and infectious disease control and prevention.²²⁴ Through these and similar efforts, governments have sought to address the underlying causes of disease and disability in populations.²²⁵

Over the last two decades, some public health experts and bioethicists have advocated a broader, more comprehensive vision of public health and its mission.²²⁶ According to this vision, the mission of public health becomes a large, all-encompassing endeavor to address a wide range of social, economic, and environmental “determinants of health” and to ensure a fair allocation of resources.²²⁷ Acting pursuant to this enlarged vision, progressives have undertaken to use government power, including its power to coerce conduct, to change socioeconomic conditions and restructure society.²²⁸

These progressives have assigned moral force to their agenda by appropriating the language and values of social justice.²²⁹ For instance, Professor Lawrence O. Gostin wrote:

Social justice is viewed as so central to the mission of public health that it has been described as the field’s core value: “The historic dream of public health . . . is a dream of social justice.” Among the most basic and commonly understood meanings of justice is fair, equitable, and

²²⁰ *See id.*

²²¹ *See id.* at 16–17, 19.

²²² *See id.* at 17.

²²³ *See id.* at 16–21.

²²⁴ *See id.* at 39.

²²⁵ *See id.* The Institute of Medicine’s influential report in 1988 defined public health as “what we, as a society, do collectively to assure the conditions in which people can be healthy.” INSTITUTE OF MEDICINE, THE FUTURE OF PUBLIC HEALTH 1 (1988).

²²⁶ *See, e.g.*, INSTITUTE OF MEDICINE, THE FUTURE OF THE PUBLIC’S HEALTH IN THE TWENTY-FIRST CENTURY (2002); NORMAN DANIELS, JUST HEALTH: A POPULATION VIEW (2007); MADISON POWERS & RUTH FADEN, SOCIAL JUSTICE: THE MORAL FOUNDATIONS OF PUBLIC HEALTH AND HEALTH POLICY (2006).

²²⁷ GOSTIN, *supra* note 219, at 39–41.

²²⁸ *Id.* at 21–23, 39–41. *See also* LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW AND ETHICS: A READER 4 (Lawrence O. Gostin, ed., University of California Press 2d ed. 2010) (“[Other scholars and practitioners] prefer a broad focus on the socioeconomic foundations of health . . . This inclusive view of public health is gaining popularity.”).

²²⁹ *See, e.g.*, GOSTIN, *supra* note 219, at 21–23.

appropriate treatment in light of what is due or owed to individuals and groups.²³⁰

The pursuit of social justice can thus inspire ambitious programs and policies to improve the health of populations and to ensure “fair” treatment by addressing “persistent patterns of systematic disadvantage” and altering social and economic conditions.²³¹

Although contraceptive methods and sterilization procedures may be prescribed for either medical or public health purposes,²³² the Administration located the contraceptive coverage mandate squarely within this broader progressive vision of public health.²³³ As the regulatory materials indicate, the Departments intended the mandate to further two large social goals: (1) public health and (2) gender equity.²³⁴ Furthermore, in the litigation before the Supreme Court, the Administration defended the mandate on public health and gender equality grounds.²³⁵

Additionally, Professor Lawrence O. Gostin, one of the foremost experts on public health law and policy in this country, framed the mandate as a public health initiative and situated it within the context of this enlarged vision. In the *Hobby Lobby Stores* litigation before the Supreme Court, Professor Gostin and other public health and foreign and comparative law experts filed an amicus brief (the Gostin

²³⁰ *Id.* at 21 (quoting Dan E. Beauchamp, *Public Health as Social Justice*, in *NEW ETHICS FOR THE PUBLIC'S HEALTH* 105-14 (Dan E. Beauchamp & Bonnie Steinbock, eds., 1999) (citing JOHN RAWLS, *A THEORY OF JUSTICE*, 10 (1971)).

²³¹ *See* GOSTIN, *supra* note 219, at 22.

²³² *See* Blum, *supra* note 218, at 8.

²³³ The IOM Committee's report reflects the public health orientation of the mandate as well as the ACA's preventive health services provisions. The Committee operated under the IOM's Board of Population Health and Public Health Practice. *See* *CLOSING THE GAPS REPORT*, *supra* note 31. The Report stated:

The passage of the [ACA] provides the United States with an opportunity to offer an unprecedented level of population health care coverage and dramatically reduce existing health disparities. The expansion of coverage to millions of uninsured Americans and the new standards for coverage of preventive services that are included in the ACA have the potential to increase the use of preventive health care services and screenings and in turn improve the health and well-being of individuals across the United States.

Id. at 15.

²³⁴ In their February 2012 rulemaking, the Departments identified “public health and gender equity” as the compelling interests served by the mandate. *Final Rules*, *supra* note 59, at 8729. In their July 2013 rulemaking, they asserted that the mandate advanced the following governmental interests: “safeguarding public health by expanding access to and utilization of recommended preventive services for women,” and “assuring that women have equal access to health care services.” *July 2013 Final Rules*, *supra* note 17, at 39,887. *See also supra* Parts II.B.5, II.B.9.

²³⁵ *See* Brief for Respondent at 10, 42, 48, *Sebelius v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 1536 (2014) (No.13-356). *See also supra* Part III.

Brief) supporting the government's position.²³⁶ The Gostin Brief highlighted the public health orientation of the mandate: "These cases present the questions whether and to what extent for-profit corporations that claim religious objection to providing health insurance plans that cover contraception can refuse to comply with a public health law as a so-called conscientious objector."²³⁷ The brief also argued that contraceptive access is "an essential component of women's human rights" and that such access "may not be circumscribed by the assertion of religious convictions by for-profit corporations."²³⁸ According to the brief, the right of women to access health care and family planning, including contraception, receives priority in foreign law sources over a limited right of conscientious objection, and conscientious objector rights are recognized only for individuals, not for-profit corporations.²³⁹ Although the Gostin Brief argued that these limitations on conscientious objection comport with the Supreme Court's religious freedom jurisprudence, the brief did not cite or discuss RFRA or RFRA's amplification of the negative right of religious freedom that is recognized in the First Amendment.²⁴⁰

B. A Brief Overview of the Analytical Framework

Professor James F. Childress, Professor Gostin, and several colleagues in the field of public health have observed that inadequate attention has been afforded to certain concepts, methods, and boundaries in public health ethics.²⁴¹ In an effort to address that deficiency, they have offered "a conceptual map of the terrain of public health ethics," which includes a set of general moral considerations and a set of justificatory conditions.²⁴² The analysis here will use their framework to evaluate the contraceptive coverage mandate as a public health initiative.

²³⁶ See Brief for Foreign and Comparative Law Experts Lawrence O. Gostin et al. as Amici Curiae Supporting Petitioners, *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014) (Nos. 13-354, 13-356).

²³⁷ *Id.* at *3.

²³⁸ *Id.* at *5.

²³⁹ *Id.* at *16–23, 30–34.

²⁴⁰ *Id.* at *28–30. The brief's presentation of the Supreme Court's religious freedom jurisprudence is highly selective.

²⁴¹ James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J. LAW, MED. & ETHICS 170 (2002). The authors of this article are an impressive team. In addition to Professors Childress and Gostin of the University of Virginia and Georgetown University respectively, the team included: Ruth R. Faden (Johns Hopkins University); Ruth D. Gaare (University of Virginia); Jeffrey Kahn (Johns Hopkins University); Richard J. Bonnie (University of Virginia); Nancy E. Kass (Johns Hopkins University); Anna C. Mastroianni (University of Washington); Jonathan D. Moreno (University of Pennsylvania); and Phillip Nieburg (Center for Strategic and International Studies).

²⁴² See *id.* at 170. Childress and his colleagues also referred to what they have proposed as "a framework." *Id.* at 177. In his book *Public Health Law: Power, Duty, Restraint*, Professor Gostin has offered another framework for systematically evaluating public health regulations. See GOSTIN, *supra* note 219, at 43–74.

1. The General Moral Considerations

In their framework, Childress and his colleagues began with the recognition that government has a duty to justify public health policies. They wrote: “In a liberal, pluralistic democracy, the justification of coercive policies, as well as other policies, must rest on moral reasons that the public in whose name the policies are carried out could reasonably be expected to accept.”²⁴³ The general moral considerations, “clusters of moral concepts and norms” that may be “variously called values, principles, or rules,”²⁴⁴ provide concrete moral guidance in evaluating particular public health policies, practices, and actions.²⁴⁵ They observed that public health activities generally have a teleological and consequentialist orientation and that the end is the public’s health.²⁴⁶ Consequently, utility-balancing factors prominently in their analytical framework, as will be evident from the discussion that follows.²⁴⁷

a. *The Nine General Moral Considerations*

Childress and his colleagues identified the following set of general moral considerations for deliberating about and justifying particular public health policies, practices, and actions:

- (1) Benefits—whether the policy or activity produces benefits;
- (2) Harms—whether the policy or activity avoids, prevents, and removes harms;
- (3) Utility—whether the policy or activity produces the maximal balance of benefits over harms and other costs;
- (4) Justice—whether the policy or activity distributes benefits and burdens fairly (distributive justice) and results from a deliberative process that

²⁴³ *Id.* at 171.

²⁴⁴ Childress et al., *supra* note 241, at 171.

²⁴⁵ *Id.*

²⁴⁶ *Id.* at 170.

²⁴⁷ Childress and his colleagues are not alone in featuring utilitarianism as a centerpiece of public health ethics. Professors Ronald Bayer and Amy L. Fairchild have argued that the values of research ethics, medical ethics, and bioethics, such as individualism, autonomy, anti-paternalism, privacy, and liberty, are fundamentally different from, and often in conflict with, the values and practices of public health ethics and that public health is “[a]nimated by a broad utilitarianism that seeks to maximize communal well-being.” Ronald Bayer & Amy L. Fairchild, *The Genesis of Public Health Ethics*, 18 *BIOETHICS* 473, 491 (2004). David Buchanan has observed that “public health has long been associated with the utilitarian school of moral philosophy. Utilitarianism is essentially consequentialist in analyzing issues, holding that the most ethically reasonable course of action is that which produces the greatest good for the greatest number.” David R. Buchanan, *Autonomy, Paternalism, and Justice: Ethical Priorities in Public Health*, 98 *AM. J. OF PUBLIC HEALTH* 15, 17 (2008). Daniel Callahan and Bruce Jennings recognized the need for dialogue between public health and bioethics and the challenges posed by “the tension produced by the predominant orientation of civil liberties and individual autonomy that one finds in bioethics, as opposed to the utilitarian, paternalistic, and communitarian orientations that have marked the field of public health throughout its history.” Daniel Callahan & Bruce Jennings, *Ethics and Public Health: Forging a Strong Relationship*, 92 *AM. J. OF PUBLIC HEALTH* 169, 170 (2002).

ensured public participation, including the participation of affected parties (procedural justice);

- (5) Autonomy/liberty—whether the policy or activity respects autonomous choices and actions, including liberty of action;
- (6) Privacy/confidentiality—whether the policy or activity protects privacy and confidentiality;
- (7) Integrity—whether policymakers have kept promises and commitments;
- (8) Transparency—whether policymakers have disclosed information and spoken truthfully; and
- (9) Trust—whether policymakers have built and maintained public trust.²⁴⁸

For Childress and his colleagues, these considerations constitute the moral content of public health ethics, but the considerations need further specification as to their meaning and scope.²⁴⁹ Moreover, each consideration provides guidance as to the appropriateness of particular policies and activities. At times, they lend support for particular policies or activities, and at other times, they counsel limitations.²⁵⁰ Additionally, some considerations may conflict with other considerations in the context of particular policies or activities.²⁵¹

b. The Balancing of General Moral Considerations of Indeterminate Weight or Strength

According to Childress and his colleagues, these general moral considerations are not absolute, and they have no specific weight or strength.²⁵² In particular instances, some considerations may need to yield to other considerations.²⁵³ Additionally, when considerations conflict, Childress and his colleagues prefer a balancing approach based upon the unique situations and contexts encountered rather than an approach of assigning priority status to certain considerations or determining their relative weights in advance.²⁵⁴ Under this balancing approach, circumstances and contexts are understood to affect the relative weights of the considerations.²⁵⁵

Although Childress and his colleagues eschew prioritizing considerations or determining their relative weights in advance of a conflict, they view the first three general moral considerations—producing benefits, preventing harms, and maximizing utility—as providing “prima facie warrant” for public health activities.²⁵⁶ Additionally, they single out justice, autonomy/liberty, and privacy/confidentiality as “particularly noteworthy.”²⁵⁷ Nevertheless, in their view,

²⁴⁸ Childress et al., *supra* note 241, at 171–72.

²⁴⁹ *Id.* at 172.

²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ *Id.*

²⁵⁷ *Id.*

each of the general moral considerations provides guidance in the process of evaluating and justifying particular public health policies and activities.

2. The Justificatory Conditions

Childress and his colleagues proposed five justificatory conditions—effectiveness, proportionality, necessity, least infringement, and public justification—to resolve conflicts among the general moral considerations.²⁵⁸ They focus primarily upon “conflict between the general moral considerations that are generally taken to instantiate the goal of public health—producing benefits, preventing harms, and maximizing utility—and those that express other moral commitments.”²⁵⁹ These justificatory conditions, they thought, could help determine “whether promoting public health warrants overriding” other considerations and values.²⁶⁰

Their five proposed justificatory conditions include some specific requirements:

- (1) Effectiveness: Proponents of a particular public health policy or activity that infringes one or more general moral considerations must show that the proposed policy or activity will realize its goal and protect public health.
- (2) Proportionality: Proponents must balance positive features and benefits against negative features and undesirable consequences and show that probable public health benefits outweigh infringed general moral considerations.
- (3) Necessity: Proponents must show that a policy or activity is necessary to realize the public health goal and adopt an effective alternative that is less problematic when available. Proponents of a coercive policy or activity carry the burden of moral proof and must show that such an approach is necessary.
- (4) Least infringement: Proponents must seek to minimize infringement of general moral considerations (a) by adopting the least restrictive or the least intrusive alternative, (b) by restricting the scope of the policy to safeguard threatened interests, and (c) by limiting the policy to the scope necessary to achieve the public health goal.
- (5) Public justification: Proponents must explain and justify any infringement of one or more general moral considerations to the relevant parties, including those adversely affected. In order to build and maintain public trust and establish public accountability, proponents must allow affected parties to provide input into the formulation of policy, and they must be transparent by treating citizens as equals and with respect by offering moral reasons that in principle they could find acceptable.²⁶¹

C. An Application of the Analytical Framework

As of the July 2013 rulemaking, the Administration imposed the contraceptive coverage mandate broadly on group health plans, health insurance issuers, and many employers, providing only a narrow religious-employer exemption and narrowly-

²⁵⁸ *Id.* at 173.

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ *Id.*

defined accommodations for non-exempt, nonprofit religious organizations that object on religious grounds.²⁶² As of the time of that rulemaking, the Administration did not exempt or accommodate any for-profit organizations that have religious or moral objections.²⁶³

1. The First Three General Moral Considerations

In their July 2010 rulemaking, the Departments discussed benefits, costs, and transfers of costs associated with the coverage of preventive services without cost sharing in general.²⁶⁴ They also discussed the estimated number of affected entities, various types of anticipated benefits, and alternatives considered regarding the rulemaking.²⁶⁵ In this rulemaking, the Departments mandated, with respect to women, coverage of preventive care and screenings provided for in comprehensive guidelines supported by HRSA.²⁶⁶ Those comprehensive guidelines regarding preventive care and screening for women, the Departments announced, were under development and expected no later than August 1, 2011.²⁶⁷ Consequently, in that rulemaking, the Departments could not have evaluated the benefits, the harms, or the utility of the contraceptive coverage mandate.

In July 2011, the IOM Committee issued its report recommending coverage of all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling.²⁶⁸ The Committee addressed scientific evidence related to this recommendation in just eight pages of its 200-plus page report.²⁶⁹ The Committee viewed unintended pregnancies (either unwanted or mistimed) as a harm and prevention of unintended pregnancies as a benefit.²⁷⁰ The Committee discussed the prevalence of unintended pregnancies and referenced documentation as to the consequences of unintended pregnancy for the mother and the baby, but it acknowledged that research is limited as to some outcomes.²⁷¹ The Committee reviewed reports and literature discussing consequences resulting from unintended pregnancies, including breastfeeding patterns, depression, happiness, birth weight, and premature birth, and it discussed contraindicated pregnancies.²⁷² The Committee also reviewed some data regarding the effectiveness of different contraceptive methods and sterilization procedures in preventing or reducing pregnancies and

²⁶² See *supra* Part II.B.9.

²⁶³ After the Supreme Court issued its ruling in the *Hobby Lobby Stores* case, the Administration proposed new rules to accommodate some for-profit businesses. See *supra* Part II.C.

²⁶⁴ See *supra* Part II.B.1 (reviewing the Departments' July 2010 rulemaking).

²⁶⁵ See *Interim Final Rules*, *supra* note 19, at 41,726, 41,730–39.

²⁶⁶ *Id.* at 41,756, 41,757–58, 41,759.

²⁶⁷ *Id.* at 41,728.

²⁶⁸ See *supra* Part II.B.2 (discussing the IOM Committee's report).

²⁶⁹ CLOSING THE GAPS REPORT, *supra* note 31, at 102–10.

²⁷⁰ *Id.* at 102.

²⁷¹ *Id.* at 102–04.

²⁷² *Id.* at 103–04.

abortion rates, and it cited the cost-effectiveness of contraception.²⁷³ The Committee acknowledged both risks and benefits of contraceptive methods, including minimal side effects and low death rates, and also noted therapeutic benefits.²⁷⁴ The Committee then referenced coverage practices in private health insurance and public insurance programs, discussing the impact of cost sharing on utilization.²⁷⁵

In his dissenting statement, Professor Lo Sasso, a health economics and health policy expert, spoke specifically to the Committee's flawed evaluation of evidence and the risk of the Committee making "poorly informed decisions" because of the unrealistic time constraints.²⁷⁶ He urged that the Committee recommend "no additional preventive services beyond those explicitly stated in the [ACA] . . . until such time as the evidence can be objectively and systematically evaluated and an appropriate framework can be developed."²⁷⁷ He was especially cognizant of the "remarkably short time frame . . . for the task of reviewing all evidence for preventive services beyond the services encompassed by [other specified entities or projects]."²⁷⁸ He observed: "As the Report acknowledges, the lack of time prevented a serious and systematic review of evidence for preventive services."²⁷⁹ The Committee erred, he thought, in its "zeal to recommend something despite the time constraints and a far from perfect methodology."²⁸⁰ For Lo Sasso, it was important that readers of the report understand that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered."²⁸¹ These deficiencies in the evidence evaluation process, he thought, were "a fatal flaw of the Report particularly in light of the importance of the recommendations for public policy and the number of individuals, both men and women, [who] will be affected."²⁸²

In addition to his concerns regarding the unrealistic time constraints and the deficient evidence evaluation process, Lo Sasso expressed concern about "the lack of a coherent framework to evaluate coverage apart from the evidence regarding clinical efficacy."²⁸³ Thus, for Lo Sasso, the Committee blurred the lines between clinical recommendations and coverage decisions, failing to differentiate properly among the materials they reviewed in terms of scientific weight.²⁸⁴

²⁷³ *Id.* at 104–09.

²⁷⁴ *Id.* at 105–07.

²⁷⁵ *Id.* at 108–09.

²⁷⁶ *Id.* at 231.

²⁷⁷ *Id.*

²⁷⁸ *Id.* at 232.

²⁷⁹ *Id.*

²⁸⁰ *Id.*

²⁸¹ *Id.* He restated this assessment in different terms: "evidence that use of the services in question leads to lower rates of disability or disease and increased rates of well-being is generally absent." *Id.*

²⁸² *Id.* at 233.

²⁸³ *Id.*

²⁸⁴ *Id.*

Law Professor Helen M. Alvaré has carefully reviewed the empirical grounds cited by the IOM Committee.²⁸⁵ Her assessment of the report and recommendation is deeply critical: “the IOM’s argument [that free contraception, sterilization, and [emergency contraceptives] are crucial for preserving women’s health] is poorly sourced, poorly reasoned, biased, and incomplete with respect to the questions of contraception and women’s health.”²⁸⁶ Her evaluation of the report concluded with the following:

In sum, the IOM Report did not prove any of the following: that it used a reliable and consistent measure of unintended pregnancy; that there is a relationship between contraceptive usage and unintended pregnancy or abortion rates; that unintended pregnancy causes poor health outcomes for women; that rates of contraceptive usage are driven by cost; or that increasing usage among the objects of the Report—employed women and the daughters of the employed—will affect rates of unintended pregnancy which are highest among women already provided with free or low-cost contraception from the government. The IOM Report also did not consider the several categories of well-developed literature bearing on the subject of the links between contraceptive usage and women’s health: physical side-effects of contraception; and the social changes effected by dissociating sex from commitment and from parenting.²⁸⁷

Soon after the IOM Committee issued its report, HRSA simply adopted the Committee’s recommendations and issued its guidelines, which had the effect of mandating the contraceptive coverage.²⁸⁸ There is no indication that HRSA conducted any separate evaluation of benefits, harms, or utility.²⁸⁹ Likewise, in their August 2011 rulemaking, the Departments did not evaluate the benefits, the harms, or the utility of the contraceptive coverage mandate, and they asserted in conclusory terms that they did not expect the amendment to the interim final rules to result in any additional significant burden or costs to the affected entities.²⁹⁰ At the time of this rulemaking, the Administration’s consideration of benefits, harms, and utility was limited to its analysis in the July 2010 rulemaking, in which the Departments could not have assessed benefits, harms, or utility of the contraceptive coverage mandate because the guidelines had not been developed.²⁹¹ Thus, as of August 2011, the evaluation of benefits, harms, and utility was limited to the IOM Committee’s deficient consideration.

The Departments’ most direct consideration of benefits occurred in their February 2012 rulemaking.²⁹² In this rulemaking, in which the Departments finalized

²⁸⁵ Alvaré, *supra* note 34, at 382–83.

²⁸⁶ *Id.* at 382. Professor Alvaré’s critical evaluation of the IOM Committee’s report is comprehensive and lengthy. *Id.* at 391–431. This Article will not undertake to perform the same critical evaluation of the IOM Committee’s report that her article does so well.

²⁸⁷ *Id.* at 431.

²⁸⁸ *See supra* Part II.B.3.

²⁸⁹ *See supra* Part II.B.3.

²⁹⁰ *Amended Interim Final Rules*, *supra* note 43, at 46,625. *See supra* Part II.B.4 (discussing the Departments’ August 2011 rulemaking).

²⁹¹ *See supra* Part II.B.1.

²⁹² *See supra* Part II.B.5 (discussing the February 2012 rulemaking).

their interim final rules, they cited various benefits, drawing primarily on the IOM Committee's report.²⁹³ The Departments did not, however, discuss any harms, such as side effects or other possible adverse consequences. As for utility, the Departments relied upon Congress's general policy that coverage of preventive services is necessary to achieve basic health care coverage.²⁹⁴ In the Departments' view, the unique health needs of women disadvantage them in the work force, and access to contraception improves the socioeconomic status of women.²⁹⁵ Additionally, the Departments expressed their beliefs that cost sharing can be a significant barrier to effective contraception and that providing women broad access to preventive services and contraceptive services reduces gender disparities.²⁹⁶ In the July 2013 rulemaking, the Departments conducted no analysis of benefits, harms, or utility of the mandate.²⁹⁷

At no point in these rulemakings did the Departments engage in a careful analysis of the benefits and the harms or the utility of including all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling in the mandated package of preventive health services. Rather, the Departments relied upon the IOM Committee to conduct whatever analysis would be conducted as to the benefits, the harms, and the utility, but, as was discussed above, the Committee's analysis itself suffers from deficiencies. Additionally, throughout these rulemakings and the development of the mandate, neither the Departments nor the IOM Committee considered the harm to human embryos that can be caused by some FDA-approved methods in some circumstances.²⁹⁸ Thus, the Administration failed to make an adequate case for the mandate based upon a careful analysis of the benefits, the harms, and the utility.

2. The Other General Moral Considerations

Even if the Administration could adequately show that the first three general moral considerations warranted its action in imposing the mandate on group health plans, health insurance issuers, and many employers, analysis of the other general moral considerations highlights additional problems with the mandate.²⁹⁹

a. Justice

While developing and implementing the mandate, the Administration considered some of the justice implications of the mandate. In the February 2012 and July 2013 rulemakings, the Departments discussed the distribution of benefits and burdens among men and women (distributive justice) and highlighted gender equity as one of

²⁹³ *Final Rules*, *supra* note 59, at 8727–28.

²⁹⁴ *Id.* at 8727.

²⁹⁵ *Id.* at 8728.

²⁹⁶ *Id.*

²⁹⁷ *See supra* Part II.B.9 (discussing the Departments' July 2013 rulemaking).

²⁹⁸ For a discussion of the acknowledgments of the federal government and drug manufacturers of the post-fertilization harm that can be caused by some FDA-approved methods, see Alvaré, *supra* note 34, at 384 & n.21, 394–95 & nn.65–78.

²⁹⁹ Because the mandate does not appear to pose a serious privacy/confidentiality concern, the analysis here does not explore that consideration.

the principal interests they were seeking to promote by creating a positive right to contraceptive coverage.³⁰⁰ Additionally, in various rulemakings, the Departments identified burdens women bear in connection with pregnancies and childbearing, and they listed perceived benefits associated with cost-free contraception and the prevention of unintended pregnancies.³⁰¹

The Administration did not, however, fully consider the concerns of justice (including social justice) when it adopted the mandate. The fundamental principle of justice is to give each person his or her due,³⁰² and what justice requires for one person cannot be determined without considering justice for others in society to whom that person relates.³⁰³ Consequently, for the Administration to address justice adequately as a general moral consideration, a broad analysis of what was due to other persons and entities was also required, and without that broad analysis, the Administration could not determine whether it was truly dispensing justice and giving to each person his or her due. A circumspect assessment of justice would also require evaluation of the effects the mandate would have on a wide range of institutions in society, including the vast numbers of religious institutions, nonprofit organizations, and businesses affected. The Administration's consideration of distributive justice was incomplete because it failed to consider carefully the burdens it was placing upon the range of individuals and entities subject to the mandate. Furthermore, the Administration was late in considering some burdens (i.e., burdens on religious organizations, nonprofit organizations, and health insurers), and it failed to consider other burdens entirely during the rulemakings (i.e., burdens on owners of for-profit companies who object on religious and moral grounds to particular contraceptive methods).³⁰⁴

As for procedural justice, the Administration decided to use procedures in developing and imposing the mandate that failed to ensure meaningful public participation, including the participation of affected parties. The Departments'

³⁰⁰ See *supra* Parts II.B.5 and II.B.9.

³⁰¹ See *supra* Parts II.B.5 and II.B.9.

³⁰² See EMIL BRUNNER, *JUSTICE AND THE SOCIAL ORDER* 23 (Mary Hottinger trans., 1945) ("From time immemorial the principle of justice has been defined as the *suum cuique*—the rendering to each man of his due."). The maxim of Roman law *suum cuique tribuere* (give to each his due), which for the Roman jurist Ulpian was one of the three basic principles of right, expresses this understanding. 1 *THE DIGEST OF JUSTINIAN* 10 (Alan Watson ed., 1985). United States Supreme Court Justice Stanley Matthews referred to this maxim as the "fundamental maxim of distributive justice." *Hurtado v. California*, 110 U.S. 516, 531 (1884).

³⁰³ See Robert John Araujo, S.J., *Our Debt to De Vitoria: A Catholic Foundation of Human Rights*, 10 *AVE MARIA L. REV.* 313, 317–18 (2012). He wrote:

In essence, the justice that is due someone or something relates to what is due others with whom this person shares society and is therefore in relationship with other persons. In other words, the justice for one cannot be determined until what is just—what is proper, and what is improper—for others involved with the same question or issue is considered and determined. In consequence, what is due one person cannot be considered until what is due others who find themselves in the same context is considered.

Id.

³⁰⁴ See *supra* Part III.A.

decisions to use the interim final rulemaking processes in their July 2010 and August 2011 rulemakings and to claim exemptions from the regular notice-and-comment rulemaking process did not comport with procedural justice.³⁰⁵ Additionally, the Administration gave critical policymaking authority to the IOM Committee, but the Committee's process failed to ensure meaningful participation by the public and interested persons and institutions.³⁰⁶ Both the Departments and the Committee could have chosen procedures that would have ensured broader and more meaningful participation, but they instead utilized processes that constricted and delayed the public's participation. As a result of the Departments' selection of rulemaking procedures, the mandate was in place upon HRSA's issuance of guidelines on August 1, 2011, before the Departments issued their first response to any of the thousands of public comments submitted in response to their July 2010 interim final rules.³⁰⁷

b. Autonomy/Liberty

In creating a positive right to contraceptive coverage, the Administration infringed the negative rights of individuals, businesses, and nonprofit and religious organizations under the First Amendment and RFRA.³⁰⁸ Additionally, by mandating coverage of preventive health services and all FDA-approved contraceptive methods and sterilization procedures, Congress and the Administration intruded upon the autonomous choices and actions of individuals, businesses, nonprofit organizations, and religious institutions.³⁰⁹ The Departments did not fully consider these

³⁰⁵ See *supra* Parts II.B.1 and II.B.4–5.

³⁰⁶ In six months, the Committee met five times and conducted three open sessions. See *supra* Part II.B.2. Professor Alvaré has provided the following observation regarding the stacking of committee membership and invited witnesses, which limited the participation of affected persons:

At least nine of the sixteen panel members had close ties with the nation's largest provider of government-subsidized birth control, and the largest abortion provider, Planned Parenthood—serving as members or even chairs of boards of directors of various Planned Parenthood affiliates nationwide. They had recently donated over one hundred thousand dollars to that organization. Others founded or worked directly for other contraception and abortion advocacy groups. Invited witnesses included Planned Parenthood, the abortion advocacy groups the National Women's Law Center, and the Guttmacher Institute. There was no representative on the panel, or as a witness, from the leading private provider of health care to women in the United States: Catholic health care services.

Alvaré, *supra* note 34, at 430–31. In addition to Catholic health care services, no representative of other groups such as Americans United for Life, Concerned Women for America, Family Research Council, and Physicians for Life was included on the panel or invited to present at a committee meeting.

³⁰⁷ See *supra* Parts II.B.3–5.

³⁰⁸ See *supra* Part III (discussing the burden imposed on religious freedom).

³⁰⁹ Professor Gostin has explained that “[a]utonomy, literally ‘self-governance,’ has acquired meanings as diverse as liberty, privacy, individual choice, and even economic freedom. . . . Autonomous persons are free to hold views, make choices, and take actions based on personal values.” GOSTIN, *supra* note 219, at 48. Gostin has recognized that government through regulation and public health activities interferes with the liberty and

infringements in their rulemaking, and what consideration they did give these infringements was years late.

c. Integrity

Reproductive rights, birth control, abortion, and women's freedom have been key pieces of President Obama's political activities, campaign promises, and policy agenda.³¹⁰ However, in November 2011, after the Departments' first two rulemakings, the IOM Committee's release of its recommendations, and HRSA's issuance of its guidelines, President Obama called Archbishop Dolan, the USCCB president, and invited him to meet to discuss issues related to the coverage of preventive services.³¹¹ In his account of their 45-minute discussion, Dolan explained that, at the conclusion of the meeting, he summarized the substance of the President's understanding as it had been conveyed to him:

I said, "I've heard you say, first of all, that you have immense regard for the work of the Catholic Church in the United States in health care, education and charity. . . . I have heard you say that you are not going to let the administration do anything to impede that work and . . . that you take the protection of the rights of conscience with the utmost seriousness. . . . Does that accurately sum up our conversation?" [Mr. Obama] said, "You bet it does."³¹²

autonomy of individuals and businesses to act in their own interests, constrains the rights of individuals and businesses, and controls individuals and businesses "for the aggregate good." *Id.* at 10–11.

³¹⁰ Alvaré, *supra* note 34, at 386–87. In her article on the mandate, Professor Alvaré chronicled some of the President's political associations and activities. *Id.* She wrote:

During his campaign, President Obama also associated himself frequently with the self-branded champion of women, and the premier promoter of a linkage between birth control, abortion, and women's freedom: the Planned Parenthood Federation of America. Planned Parenthood donated 15 million dollars of campaign advertisements to the President's re-election campaign. And the President continued strenuously to support both federal and state grants for Planned Parenthood, for hundreds of millions dollars annually, as well as to deploy his Administration's Department of Justice to states where legislatures had re-directed their family planning funds away from local Planned Parenthoods, in favor of providers without an abortion connection. The Department of Justice threatened these states with the withdrawal of all federal Medicaid funding for all services for the poor. Very likely, President Obama's close association with Planned Parenthood strengthened his campaign's and his Administration's publicity regarding their support for women. It also raised questions about the objectivity of the Mandate and the Report supporting it—both of which were mirror images of Planned Parenthood's agenda, and that of its former research affiliate, the Guttmacher Institute, respecting contraception and religious objectors.

Id. at 387. *See supra* note 28 (discussing the links between the Administration, abortion providers, and the manufacturer of Plan B).

³¹¹ *See supra* Part II.B.5 (discussing the meeting between President Obama and Archbishop Dolan).

³¹² Taranto, *supra* note 63.

President Obama gave Dolan permission to share that message with the other bishops.³¹³

Two months later, in January 2012, President Obama called Archbishop Dolan “to say that the mandates remain in place and that there would be no substantive change, and that the only thing he could offer [the archbishop] was that [the Catholic Church and its institutions] would have until August.”³¹⁴ In his account of this call, Dolan explained:

I said, “Mr. President, I appreciate the call. Are you saying now that we have until August to introduce to you continual concerns that might trigger a substantive mitigation in these mandates?” He said, “No, the mandates remain. We’re more or less giving you this time to find out how you’re going to be able to comply.” I said, “Well, sir, we don’t need the [extra time]. I can tell you now we’re unable to comply.”³¹⁵

A few weeks later, in the wake of a strong public response to the Administration’s hard-lined approach, President Obama called Archbishop Dolan to indicate that the Administration was developing a plan to shift the cost of paying for the mandated coverage to insurers.³¹⁶

In February 2012, the Departments finalized the interim final rules, adopting them without any substantive change.³¹⁷ At the same time, the Administration announced the one-year enforcement safe harbor for non-exempt, nonprofit religious organizations with religious objections and its plan to develop narrowly defined accommodations.³¹⁸

d. Transparency

The Departments’ decision to adopt the mandate through interim final rulemakings in July 2010 and August 2011, and their reliance on exemptions from the standard notice-and-comment rulemaking process, thwarted transparency in the adoption of the mandate.³¹⁹ Additionally, the Administration decided to use a sympathetic IOM Committee to provide a favorable sifting of evidence and to put a medical- and social-scientific veneer on the Administration’s political and policy commitments.³²⁰ Consequently, the IOM Committee recommendation process afforded the Administration a forum to ensure the success of its desired policy outcomes, while giving the appearance of openness, scientific grounding, and

³¹³ *Id.*

³¹⁴ *Id.*

³¹⁵ *Id.*

³¹⁶ *Id.* Archbishop Dolan was elevated to cardinal on February 18, 2012, which was after his meeting and conversations with the President but before this account was published in *The Wall Street Journal*. *Id.*

³¹⁷ *See supra* Part II.B.5.

³¹⁸ *See supra* Part II.B.5.

³¹⁹ *See supra* Parts II.B.1 and II.B.4.

³²⁰ *See supra* Part II.B.2.

meaningful deliberation and obtaining the political and legal advantages that come from the endorsement of an “independent expert” panel.³²¹

The Committee itself did not ensure transparency and information disclosure in its work, and the Committee’s membership and invited witnesses failed to represent the broader array of public views on the issues.³²² In his dissenting opinion, Professor Lo Sasso observed:

[T]he committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee’s composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy. An abiding principle in the evaluation of the evidence and the recommendations put forth as a consequence should be transparency and strict objectivity, but the committee failed to demonstrate these principles in the Report.³²³

e. Trust

The procedures used by the Administration and the substantive policy developed did not build and maintain public trust. Rather, the Administration’s infringements of religious freedom and conscience, the way in which it went about developing and imposing the mandate, its delay in exempting religious employers and accommodating non-exempt, nonprofit religious organizations with religious objections, and the narrowness of the religious-employer exemption and accommodations likely contributed to some of the decline President Obama has experienced in trustworthiness.³²⁴

³²¹ See U.S. Dep’t of Health and Human Servs, News Release, *Affordable Care Act Ensures Women Receive Preventive Services at No Additional Cost* (Aug. 1, 2011), <http://wayback.archive-it.org/3926/20140108162111/http://www.hhs.gov/news/press/2011pres/08/20110801b.html> (“HHS directed the independent Institute of Medicine to, for the first time ever, conduct a scientific review and provide recommendations on specific preventive measures that meet women’s unique health needs and help keep women healthy. HHS’ Health Resources and Services Administration (HRSA) used the IOM report issued July 19, when developing the guidelines that are being issued today. The IOM’s report relied on independent physicians, nurses, scientists, and other experts to make these determinations based on scientific evidence.”). The Institute of Medicine, the health arm of the National Academy of Sciences, is “an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.” See *About the IOM*, INST. OF MED.EDU, <http://www.iom.edu/About-IOM.aspx> (last visited Jan. 25, 2015). Although the National Academies are “independent,” about eighty-five percent of their funding comes from the federal government through contracts and grants from federal agencies. See Div. on Eng’g and Physical Scis., *DEPS—Frequently Asked Questions*, NAT’L ACAD. OF SCI.ORG, http://sites.nationalacademies.org/DEPS/DEPS_037300 (last visited Jan. 25, 2015). The funding that supported the IOM Committee’s work on the report and recommendations on preventive services for women came from HHS’s Office of the Assistant Secretary for Planning and Evaluation. See *supra* note 3128 and accompanying text.

³²² See *supra* Part II.B.2 and notes 306, 310 (discussing committee members and invited witnesses).

³²³ CLOSING THE GAPS REPORT, *supra* note 31, at 232–33.

³²⁴ Susan Heavey/Reuters, *Majority of Americans Think Obama Is not Honest or Trustworthy: Poll*, HUFFINGTON POST, Nov. 25, 2013, available at

3. The Justificatory Conditions

Analysis of the mandate under the general moral considerations shows both the Administration's failure to demonstrate that the mandate was warranted based upon the benefits, the harms, and the utility, and the conflict that exists between the benefits, the harm prevention, and the utility claimed by the Administration and the other general moral considerations proposed by Childress and his colleagues.³²⁵ Consequently, under the framework of Childress and his colleagues, further analysis is required based on the justificatory conditions, and the Administration, as the proponent of the public health initiative, would bear the burden of justifying the mandate.

a. Effectiveness

In their rulemakings, the Departments did not demonstrate the mandate's effectiveness. In the July 2010 rulemaking, for instance, the Departments discussed the new coverage requirements in the ACA, the ACA's and the Administration's general policy favoring utilization of preventive services, factors that contributed to underutilization of preventive services, and benefits expected to result from the coverage mandates.³²⁶ In this rulemaking, however, the Departments did not specifically show that the contraceptive coverage mandate would protect public health or that the mandate would realize the Departments' goals, which they did not articulate until their February 2012 rulemaking.³²⁷ Likewise, in the August 2011 rulemaking, the Departments did not make any such effectiveness showing.³²⁸

In its report, the IOM Committee discussed the effectiveness and cost-effectiveness of contraceptive methods, sterilization procedures, and patient education and counseling in preventing pregnancies.³²⁹ Although the Committee noted coverage practices in private and public health insurance and some existing coverage recommendations, the Committee did not show that the clinical effectiveness of methods and procedures would result in the achievement of the Administration's public health and gender equity goals or that the mandated coverage would achieve the Administration's identified goals.³³⁰ The closest the Committee came to this type of effectiveness assessment is found in the following statements:

http://www.huffingtonpost.com/2013/11/25/obama-poll_n_4337643.html. In a November 2013 poll, which was released just four months after the Administration issued the final rules on the mandate, the religious-employer exemption, and the accommodations, 53 percent of those polled indicated that the President was not honest or trustworthy, which "mark[ed] the first time that the CNN/ORC polling found a clear majority questioning the president's integrity." *Id.*

³²⁵ See *supra* Parts IV.C.1–2.

³²⁶ See *supra* Part II.B.1; *Interim Final Rules*, *supra* note 19, at 41,730–38.

³²⁷ See *supra* Part II.B.5; *Final Rules*, *supra* note 59, at 8,728–29.

³²⁸ See *supra* Part II.B.4; *Amended Interim Final Rules*, *supra* note 43, at 46,621.

³²⁹ See CLOSING THE GAPS REPORT, *supra* note 31, at 104–09.

³³⁰ *Id.* at 108–09.

It is *thought* that greater use of long-acting, reversible contraceptive methods—including intrauterine devices and contraceptive implants that require less action by the woman and therefore have lower use failure rates—*might* help further reduce unintended pregnancy rates . . . The elimination of cost sharing for contraception therefore *could* greatly increase its use, including use of the more effective and longer-acting methods, especially among poor and low-income women most at risk for unintended pregnancy.³³¹

In his dissenting statement, Professor Lo Sasso identified a fundamental flaw in the Committee’s effectiveness assessment – the Committee “lack[ed] . . . a coherent framework to evaluate coverage apart from the evidence regarding clinical efficacy.”³³² The Committee’s inability to evaluate the effectiveness of the contraceptive coverage mandate may stem from this methodological deficiency, as well as the fact that the Committee had “barely six months from the time the group was empanelled” to review all evidence of preventive services and issue the final report.³³³

Accordingly, the Administration did not make the necessary showing that the mandate was likely to protect public health and achieve gender equity. This failure undercuts its justification for infringing one or more general moral considerations.

b. Proportionality

In the July 2010 and August 2011 rulemakings, the Departments did not show that the probable public health benefits outweighed the infringed general moral considerations (such as breached autonomy/liberty).³³⁴ Indeed, these rulemakings do not reveal much of any willingness on the part of the Departments to acknowledge that the mandate caused any infringement. However, in the August 2011 rulemaking, the Departments acknowledged that an exception was warranted for a very narrow class of religious employers, and they expressed their view that this narrow definition “reasonably balance[d]” their goal of extending coverage broadly with “respecting the unique relationship between certain religious employers and their employees in certain religious positions.”³³⁵ Implicit in the Departments’ discussion was an assumption that the benefits outweigh any other infringement, and thus the Departments did not assign relative weights or weigh perceived benefits against any other infringement.

In the February 2012 rulemaking, the Departments gave more attention to the claimed benefits of the mandate and to possible infringements.³³⁶ In this rulemaking, the Departments addressed, for the first time, conscience protections in federal laws, the religious beliefs of organizations and individuals other than those in their

³³¹ *Id.* at 108–09 (emphasis added).

³³² *Id.* at 233.

³³³ *Id.* at 232.

³³⁴ *See supra* Parts II.B.1 and II.B.4.

³³⁵ *Amended Interim Final Rules*, *supra* note 43, at 46,623.

³³⁶ *See supra* Part II.B.5.

narrowly defined class of religious employers, the First Amendment, and RFRA.³³⁷ The Departments' announcement of the one-year enforcement safe harbor and their plan to develop accommodations for non-exempt, nonprofit religious organizations with religious objections may constitute something of a concession regarding possible infringements.³³⁸ But, in any event, they deemed their interests compelling and concluded that their approach was consistent with the First Amendment and RFRA.³³⁹ Consequently, the Departments failed to provide a careful assessment of proportionality between the claimed benefits and the infringements. Instead, the Departments manifested a commitment to retain the mandate, which was already in effect, and a willingness to make only minor adjustments for narrowly defined classes of religious employers and non-exempt, nonprofit religious organizations with religious objections.³⁴⁰

In the July 2013 rulemaking, the Departments gave more attention to the First Amendment and RFRA issues, but their assessment extended only to questions related to religious employers and non-exempt, nonprofit religious organizations with religious objections.³⁴¹ In the regulatory materials, they expressed their view that the accommodations did not violate RFRA and that the religious-employer exemption and the accommodations did not violate the First Amendment.³⁴²

The various rules adopted by the Departments and the accompanying regulatory materials do not evidence a fulsome balancing of all positive features and benefits against the negative features and consequences. To the extent that a proportionality assessment was performed, it was late, and it was restricted to a narrow class of religious employers and narrowly-defined accommodations of non-exempt, nonprofit religious organizations with religious objections. At no time did the Departments perform a proportionality assessment as to for-profit organizations. Accordingly, proponents of the mandate failed to make the requisite showing that the probable public health benefits outweighed infringed general moral considerations.

c. Necessity and Least Infringement

In their rulemakings, the Departments failed to show that the required coverage of all FDA-approved contraceptive methods, sterilization procedures, patient education and counseling was necessary to realize the Administration's public health and gender equity goals, and they were late in addressing whether less infringing or less restrictive alternatives were available.³⁴³ Judging from the rulemakings and regulatory materials, it does not appear that the Department sensed an obligation to address questions of necessity and less infringing alternatives as to contraceptive

³³⁷ See *supra* Part II.B.5.

³³⁸ It may simply reflect election year politics, as 2012 was a presidential election year. See *supra* note 139.

³³⁹ See *supra* Parts II.B.5 and III.A.

³⁴⁰ See *supra* Parts II.B.5, II.B.7, II.B.8, and II.B.9.

³⁴¹ See *supra* Parts II.B.9 and III.A.

³⁴² See *supra* Parts II.B.9 and III.A.

³⁴³ Childress and his colleagues indicated that the justificatory condition of least infringement may be understood as a corollary of the justificatory condition of necessity. Childress et al., *supra* note 241, at 172. They will be so treated here.

coverage, perhaps in part because the ACA mandated coverage of preventive health services. The issues should not, however, be conflated because Congress did not require that all FDA-approved contraceptive methods and sterilization procedures be included within the package of covered preventive health services.³⁴⁴

In the July 2010 rulemaking, the Departments discussed the ACA coverage requirements, the ACA's and the Administration's general policy favoring utilization of preventive services, factors that contributed to underutilization of preventive services, and benefits expected to result from the coverage mandates generally.³⁴⁵ The Departments referenced the need to address market failures that lead to underutilization of preventive services and barriers that result from cost sharing.³⁴⁶ The Departments also asserted that their rules were necessary because plan sponsors and issuers needed to know how to provide the coverage without cost sharing.³⁴⁷ In conclusory terms, the Departments asserted that their rules regarding coverage of preventive services were "designed to be the least burdensome alternative."³⁴⁸

Neither the IOM Committee nor HRSA assessed whether the contraceptive coverage mandate was necessary to realize the Administration's goals. Indeed, one of the criticisms highlighted by Professor Lo Sasso in his dissenting opinion was the Committee's failure to show that the services will accomplish the desired goals, let alone that the coverage mandate was necessary to realize the Administration's public health and gender equity goals: "[T]he [Committee's] recommendations were made without high quality, systematic evidence of the preventive nature of the services considered. Put differently, evidence that use of the services in question leads to lower rates of disability or disease and increased rates of well-being is generally absent."³⁴⁹ Additionally, neither the IOM Committee nor HRSA evaluated alternative means of realizing the goals.

Likewise, in their August 3, 2011 rulemaking, the Departments did not closely scrutinize the necessity of the contraceptive coverage mandate to realize the Administration's public health goals or evaluate alternative means of realizing the public health goals apart from the mandate.³⁵⁰ As the "need" for regulatory action in this rulemaking, the Departments cited their assessment that an amendment to the interim final rule was warranted to provide HRSA discretion to exempt certain religious employers.³⁵¹

³⁴⁴ See *supra* Part II.A.

³⁴⁵ See *supra* Parts IV.C.1 and IV.C.3.a.

³⁴⁶ *Interim Final Rules*, *supra* note 19, at 41,731.

³⁴⁷ *Id.*

³⁴⁸ *Id.* at 41,739. By choosing to use the interim final rulemaking process, the Departments sidestepped some of the analyses that would be required under federal law, such as analyses under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act. The Departments did provide a conclusory assessment that their rules were "consistent with the policy embodied in the Unfunded Mandates Reform Act." *Id.*

³⁴⁹ CLOSING THE GAPS REPORT, *supra* note 31, at 232.

³⁵⁰ See *supra* Part II.B.4.

³⁵¹ *Amended Interim Final Rules*, *supra* note 43, at 46,625.

With the February 2012 rulemaking, the Departments, in response to the high volume of comments that had been submitted, began to think about some alternatives as they considered accommodations for non-exempt, nonprofit religious organizations with religious objections.³⁵² Although the Departments' development of accommodations does represent an effort to minimize some infringement caused by the mandate, the accommodations had a narrow scope, and the accommodations did not extend beyond the narrow class of organizations identified by the Departments.³⁵³

In the July 2013 rulemaking, the Departments finalized the rules regarding the religious-employer exemption and the accommodations, and they directly addressed alternatives to the mandate.³⁵⁴ Commenters on the Departments' February 2013 proposed rules had suggested various alternatives to the mandated contraceptive coverage: the government could provide contraceptive services to all women free of charge; the government could establish a government-funded health benefits program for contraceptive services; the government could require drug and device manufacturers to provide contraceptive drugs and devices free of charge; and the government could require multi-state plans on the exchanges to offer a stand-alone, contraceptive-only benefit to all women without charge.³⁵⁵

The Departments offered several responses. First, the suggested alternatives "were not feasible and/or would not advance the government's compelling interests as effectively as the mechanisms established" in the final rules and the preventive health services coverage regulations generally.³⁵⁶ Second, the Departments lacked the statutory authority and funding to implement the proposed alternatives.³⁵⁷ Third, the ACA contemplates that the existing employer-based system of health insurance would provide coverage of recommended preventive services so that "women face minimal logistical and administrative obstacles."³⁵⁸ Fourth, imposing additional requirements on women receiving the intended coverage "would make that coverage accessible to fewer women."³⁵⁹ Although these responses addressed alternatives proposed by commenters, the responses were conclusory, and the Departments did not otherwise attempt to find a less infringing or less restrictive alternative.

Because of the Administration's failure to address carefully questions of necessity and less infringing alternatives, the mandate was challenged in dozens of cases throughout the nation.³⁶⁰ As discussed earlier, the Supreme Court eventually determined that the Administration failed to show that the mandate was the least

³⁵² See *supra* Part II.B.5.

³⁵³ In response to the Supreme Court's ruling in the *Hobby Lobby Stores* case, the Administration has proposed new rules that will expand the class of organizations that qualify for an accommodation. See *supra* Part II.C and III.D.

³⁵⁴ See *supra* Part II.B.9 and III.A.

³⁵⁵ See *July 2013 Final Rules*, *supra* note 17, at 39,888.

³⁵⁶ *Id.*

³⁵⁷ *Id.*

³⁵⁸ *Id.*

³⁵⁹ *Id.*

³⁶⁰ See *supra* Parts I and III.

restrictive means of furthering the claimed interests.³⁶¹ According to the Court, the Administration had “not shown that it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting parties in these cases.”³⁶² The Court added:

The most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers’ religious objections. This would certainly be less restrictive of the plaintiffs’ religious liberty, and [the Administration] has not shown that this is not a viable alternative.³⁶³

Under the framework proposed by Childress and his colleagues, the Administration failed to justify the mandate by showing both that it was necessary to realize the public health goals and that it was the least infringing or the least restrictive option among alternatives. These were showings that the Administration was required to make as the proponent of this public health policy, especially given the coercive nature of the mandate.

d. Public Justification

The Departments chose to use the interim final rulemaking process (and not the standard notice-and-comment rulemaking process in its first two rulemakings) and to make use of an IOM Committee partially composed of representatives of pro-choice advocacy groups that had a short timeframe in which to generate a report and recommendations.³⁶⁴ By making these choices, the Departments accelerated the rulemaking process, but they also suppressed public participation. By sidestepping the standard notice-and-rulemaking process, the Departments missed important opportunities both to gain the benefit of feedback from the public and interested persons and to provide a public justification for the mandate. Although the Departments’ manipulation of the rulemaking process ensured their success in putting the mandate in place upon HRSA’s adoption of the IOM Committee’s hurriedly-prepared report and recommendations and HRSA’s issuance of its guidelines, the process they selected gave the public limited opportunity for input and required the Departments to provide only limited justification for their mandate.

Such manipulation of process runs directly counter to the understanding of Childress and his colleagues regarding public justification and public accountability in public health activities.³⁶⁵ Under their framework, the federal government was to ensure a public process that included proposals, justifications, deliberation, feedback, reconsideration, and a final decision.³⁶⁶ Additionally, Childress and his colleagues

³⁶¹ See *supra* Part III.C.

³⁶² *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2780 (2014).

³⁶³ *Id.* (internal citation omitted).

³⁶⁴ See *supra* Parts II.B.1–4.

³⁶⁵ Childress et al., *supra* note 241, at 173–75.

³⁶⁶ *Id.* at 174. Childress and his colleagues noted that public accountability, which they understood to include public justification, “involves soliciting input from the relevant publics

wrote: “the public, along with scientific experts, plays an important role in the *analysis* of public health issues, as well as in the development and assessment of appropriate *strategies* for addressing them.”³⁶⁷

In the case of the mandate, the Departments restricted the public’s participation both in the analysis of the issues and in the development and assessment of appropriate strategies. The Administration also failed to explain and justify the infringement of one or more general moral considerations. To the extent that the Administration provided justification to the public and to the individuals, religious institutions, nonprofit organizations, and businesses burdened by the mandate for its infringement of one or more general moral considerations, the justification was late and lacking. Thus, with public justification, as with the other justificatory conditions, the Administration failed to make the requisite showing.

D. The Administration’s Failure of Deliberation and Justification in This Public Health Initiative

An application of the framework proposed by Childress and his colleagues suggests significant deficiencies in the Administration’s deliberation regarding, and justification of, the mandate. The Departments failed to evaluate various general moral considerations, recognize the conflicts among considerations caused by the mandate, and provide an adequate public justification of their public health initiative and their infringement of important values. In the final analysis, this public health initiative began poorly with the Departments’ decision to proceed by interim final rulemaking—not just once, but twice—and public and transparent deliberation about and justifications for the mandate have been very slow in coming. This is hardly what Childress and his colleagues contemplated in their framework for carefully evaluating public health policies, practices, and activities and resolving conflicts among moral considerations.

V. CONCLUSION

This Article has analyzed the contraceptive coverage mandate from three perspectives. It explored the rulemaking processes used by executive departments of the federal government in developing the mandate, including their use of an IOM Committee to develop recommendations. This analysis highlighted the Obama Administration’s decisions to bypass standard regulatory procedures and instead to use the interim final rulemaking process, which restricted public participation in the development of the rules and hampered transparency and deliberation in the rulemaking process. This Article also analyzed the mandate under the framework that Congress mandated in RFRA. This analysis showed that the Departments overlooked this legal standard in its first several rulemakings and failed to consider carefully the burden their mandate placed on the negative right of religious freedom. Finally, this Article analyzed the mandate under the public health policy and ethics

(the numerical, political, and communal publics) in the process of formulating public health policies, practices, and actions, as well as justifying to the relevant publics what is being undertaken.” *Id.* at 173. Additionally, “[a]t a minimum, public accountability involves transparency in openly seeking information from those affected and in honestly disclosing relevant information to the public; it is indispensable for engendering and sustaining public trust, as well as for expressing justice.” *Id.*

³⁶⁷ *Id.* at 174 (emphases in original).

framework proposed by Professor Childress and his colleagues. This analysis showed that the Administration's deliberation failed to address adequately several general moral considerations and conflicts among considerations and failed to justify the mandate's infringements.

In addition to providing these three analyses, this study has also provided insight regarding the moral decision-making inherent in policymaking and lawmaking and in the public health enterprise. The mandate is a piece of progressive "legislation."³⁶⁸ It was not enacted by the duly-elected representatives of the American people. Rather, the mandate was made through the sorts of administrative rulemaking processes that progressives have preferred for the better part of a century: "administratively organized 'communities' of highly trained, objective professionals" with quasi-legislative powers making rules based upon "unbiased" physical and social sciences, technical expertise, and empirical data with the goal of leading society forward and bringing about transformative social, legal, and economic reforms.³⁶⁹ The mandate (and the Administration's arguments defending against challenges to the mandate) also exhibited the longstanding opposition of progressives to the interests of businesses and business owners who are viewed as obstacles to social progress.³⁷⁰

This progressive approach to policymaking and lawmaking obscures some of the moral decision-making inherent in such regulatory activity, but the analytical framework of Childress and his colleagues helps to reveal more fully the moral decision-making that is in fact involved. As discussed above, public health activities are often understood to have a teleological or consequentialist orientation.³⁷¹ And, in the framework proposed by Childress and his colleagues, consequentialism is evident in their first three general moral considerations: producing benefits, preventing harms, and maximizing utility (i.e., the balance of benefits over costs).³⁷² Professor Gostin agrees that moral decision-making lies at the heart of public health policymaking:

Since a principal aim of public health is to achieve the greatest health benefits for the greatest number of people, it draws from the traditions of consequentialism, which judges the rightness of an action by the consequences, effects, or outcomes that it produces. Utilitarianism, one of the most influential forms of consequentialist ethical theory, holds that actions are justified insofar as they promote the greatest happiness of the greatest number of people.³⁷³

³⁶⁸ Although the mandate is not technically legislation passed by a legislative body, in administrative law parlance the rules that promulgated the mandate are legislative rules. *See* Am. Tort Reform Ass'n v. Occupational Safety & Health Admin., 738 F.3d 387, 395 (D.C. Cir. 2013) ("Notice and comment rulemaking procedures are required under the [Administrative Procedure Act] when substantive rules are promulgated, modified, or revoked. Substantive or legislative rules are those that grant rights, impose obligations, or produce other significant effects on private interests, or which effect a change in existing law or policy.") (quotation marks and citations omitted).

³⁶⁹ *See* Schwartz, *supra* note 11, at 820.

³⁷⁰ *See generally supra* note 11.

³⁷¹ *See supra* Part IV.B.

³⁷² *Id.*

³⁷³ GOSTIN, *supra* note 228, at 14.

Although the mandate is encased in regulatory, social scientific, medical, and public health terminology, the analytical framework proposed by Childress and his colleagues helps to show that the regulations and the mandate itself are predicated upon moral judgments and reflect a moral vision. The moral underpinnings of the mandate become apparent when the Administration's utilitarian calculus is isolated: the interests in public health and gender equity are compelling and outweigh the less weighty interests that individuals, institutions, and organizations coerced by the mandate might have in religious liberty, conscience, and economic freedom. True to its public health goals, the Administration in its mandate favored a population over individuals.

For the Administration, the perceived benefits outweighed the costs. In the rulemakings and accompanying regulatory materials, the Administration lauded the anticipated benefits of readily-accessible preventive services, including a healthier population, disease prevention, earlier treatment, and reduced health care costs. Drawing on the IOM Committee's report, it cited various possible benefits: meeting the basic health care needs of women; preventing unintended pregnancies (whether unwanted or mistimed); promoting healthy birth spacing; avoiding contraindicated pregnancies; saving employers pregnancy-related costs and costs related to absences and reduced productivity; removing the out-of-pocket-expense barrier to effective contraception; helping women achieve equal standing in the workforce; and improving the socio-economic status of women. The Administration retained a narrow religious-employer exemption because it believed a broader exemption would lead to more employees paying out of pocket for contraceptive services, which would make it less likely that employees would have access to and use contraceptives.

The Administration deemed the costs to be minor. It asserted that the mandate does not undermine religious and conscience exemptions in federal law and that the rules are consistent with the First Amendment and RFRA. In the February 2012 rulemaking, the Administration's utility balancers asserted in conclusory terms that its "approach complies with [RFRA], which generally requires a federal law to not substantially burden religious exercise, or, if it does substantially burden religious exercise, to be the least restrictive means to further a compelling government interest."³⁷⁴ Thus, even RFRA's strict scrutiny standard posed no problem for the mandate because the Administration viewed the claimed interests as compelling. In the end, forcing individuals and organizations to violate the religious beliefs or conscience did not have much weight for the Administration's utility balancers.

On its face, utilitarian balancing (such as was used by the Administration in adopting the mandate) appears objective and capable of leading to indisputable conclusions. But, in reality, such moral reasoning leads to preordained conclusions that conform to the values of decision-makers. In other words, utilitarian balancing affords policymakers an opportunity to put their own thumbs on the scale as they import their own values and assign their values more weight and opposing values less weight. It appears that this is precisely what happened in the development of the mandate.

Furthermore, this mode of moral decision-making emphasizes immediate and concrete interests, while deemphasizing or ignoring more remote, more abstract, or

³⁷⁴ *Final Rules*, *supra* note 59, at 8729.

less convenient interests.³⁷⁵ In the case of the mandate, the Administration's analysis gave no weight to the status of the unborn, even though several FDA-approved contraception methods prevent fertilized eggs (human embryos) from implanting in the uterus. The moral concerns of Americans who understand these methods to constitute abortion, and not contraception, were given little or no weight by the Administration.³⁷⁶

For the Administration and present-day progressives, health care reform has been a moral undertaking,³⁷⁷ and the contraceptive coverage mandate is an integral part of their larger moral endeavor. The mandate is predicated upon the Administration's moral judgments, and once we acknowledge that the Administration in promulgating the mandate legislated morality, we can more clearly identify the contours of the Administration's moral vision—its vision of the good and the just society—that

³⁷⁵ Justice William J. Brennan, Jr. offered a similar assessment in his criticism of the Supreme Court's use of a balancing test to determine whether Congress violated Article III of the Constitution by delegating power to an agency to adjudicate some common-law claims. Justice Brennan stated:

[Balancing] pits an interest the benefits of which are immediate, concrete, and easily understood against one, the benefits of which are almost entirely prophylactic, and thus often seem remote and not worth the cost in any single case. Thus, while balancing creates the illusion of objectivity and ineluctability, in fact the result was foreordained, because the balance is weighted against judicial independence.

Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 863 (1986) (Brennan, J., dissenting).

³⁷⁶ The USCCB has made its moral and religious objections to abortion and abortifacient drugs and devices widely known. See USCCB, DOES THE HHS MANDATE INCLUDE ABORTIFACIENTS? (Apr. 3, 2014), <http://usccb.org/issues-and-action/human-life-and-dignity/contraception/upload/Does-the-HHS-Mandate-Include-Abortifacients.pdf>. The Catholic Church in the United States has nearly 70 million members, and it is the largest religious group in the country. See Hartford Inst. for Religious Research, *Fast Facts About American Religion*, HARTFORD INST. FOR RELIGIOUS RESEARCH, http://hrr.hartsem.edu/research/fastfacts/fast_facts.html (last visited Jan. 25, 2015). In a recent poll, fifty-eight percent of respondents say that abortion should be illegal or legal in few circumstances, and fifty-six oppose the use of public funds for abortions for women who cannot afford them. See *CNN Poll: Wide Divide over Abortion*, CNN (Mar. 6, 2014), <http://politicalticker.blogs.cnn.com/2014/03/06/cnn-poll-wide-divide-over-abortion/>. In another recent poll, thirty-five percent of respondents agreed that employers should be able to choose the forms of contraceptives their health plans cover based on their religious beliefs. See Joan Biskupic, *A Majority of Americans Oppose Restrictions on Contraceptive Insurance Coverage, Says Poll*, CHRISTIAN SCI. MONITOR (June 30, 2014), <http://www.csmonitor.com/USA/Latest-News-Wires/2014/0630/A-majority-of-Americans-oppose-restrictions-on-contraception-insurance-coverage-says-poll-video>. In an earlier poll, fifty percent of respondents expressed disapproval of the Administration's contraceptive coverage mandate. See *CNN Poll: Half Oppose Obama Birth Control Insurance Plan*, CNN (Feb. 16, 2012), <http://politicalticker.blogs.cnn.com/2012/02/16/cnn-poll-half-oppose-obama-birth-control-insurance-plan/>. In another poll, fifty-one percent favored allowing employers to opt out of birth control coverage for moral or religious reasons. See *N.Y. Times/CBS News Poll: President Obama's Approval Rating Drops*, N.Y. TIMES (Mar. 12, 2012), http://www.nytimes.com/interactive/2012/03/13/us/politics/president-obamas-approval-rating-drops.html?ref=politics&_r=0.

³⁷⁷ See *supra* notes 11 and 12.

inspired the development of and is embedded within the mandate. The mandate is meant to change economic and social structures, and it advances the Administration's vision of social justice. It also advances the Administration's vision of women's freedom and gender equity by requiring businesses, institutions, and individuals to fund the provision of broad and free access to FDA-approved contraceptive, sterilization, and family planning services. Additionally, the mandate is premised upon the moral values of the policymakers regarding the family, human sexuality, and the status of the unborn. Furthermore, the mandate expresses the Administration's moral judgment that its vision of public health and gender equity should be advanced even at the expense of religious freedom, matters of conscience, and the economic freedom of individuals and organizations.

Professor Gostin has warned, however, that the legitimacy of the public health enterprise is threatened when the enterprise becomes captive to ideology and political advocacy.³⁷⁸ He wrote: "By espousing controversial issues of economic redistribution and social restructuring, the field risks losing its legitimacy. Public health gains credibility from its adherence to science, and if it strays too far into political advocacy, it may lose the appearance of objectivity."³⁷⁹ It may be that the Administration's mandate (along with its failures in reasoned deliberation, fair and transparent process, and respect for autonomy and liberty, and its failures to maintain public trust and provide public justification) will become a prime example of a public health initiative delegitimized by the actions of its proponents.

³⁷⁸ GOSTIN, *supra* note 219, at 495 ("To maintain legitimacy and trust, public health authorities rely on expert knowledge derived from the science of public health. Scientific decisions are thought to be more objective and systematic, and less captive to political ideology.").

³⁷⁹ *Id.* at 41.