NOS. 19-431, 19-454

IN THE
Supreme Court of the United States

LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,
Petitioners,
v.
PENNSYLVANIA, *ET AL.*,
Respondents.

DONALD J. TRUMP, PRESIDENT OF THE UNITED STATES, *ET AL.*,
Petitioners,
v.
COMMONWEALTH OF PENNSYLVANIA, *ET AL.*,
Respondents.

On Writ of Certiorari
To the United States Court of Appeals
For the Third Circuit

BRIEF FOR THE AMERICAN ACADEMY OF PEDIATRICS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

DEVI M. RAO
Counsel of Record
JENNER & BLOCK LLP
1099 New York Avenue NW
Washington, DC 20001
(202) 637 6390
drao@jenner.com

Counsel for Amicus Curiae

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INTEREST OF *AMICUS CURIAE*[1]

The American Academy of Pediatrics ("AAP") was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. Since AAP's inception, its membership has grown from 60 physicians to over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 90 years, AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. Among other things, AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's children and adolescents to ensure the availability of safe and effective vaccines and contraceptives.

Under a cooperative agreement with the Health Resources and Services Administration ("HRSA"), the AAP develops pediatric care guidelines. Since 2001, supported by HRSA, AAP has drafted the comprehensive guidelines for pediatric health supervision visits and preventive services, known as *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents* ("*Bright Futures*") and accompanying periodicity schedule, *Bright Futures/AAP Recommendations for Preventive*

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[1] No person or entity other than Amicus and its counsel made a monetary contribution to the preparation or submission of this brief. No counsel to a party authored this brief in whole or in part. Petitioners and Respondents have consented to the filing of this brief, as reflected in the blanket consent statements filed with the Clerk of Court.

Pediatric Health Care. *See* 42 U.S.C. § 300gg-13(a)(3). *Bright Futures* began in 1994 as a set of recommended guidelines for children's healthcare, prepared by a group of pediatric health care experts and family representatives in consultation with the Maternal and Child Health Bureau, HRSA, and the Medicaid Bureau (now the Centers for Medicare & Medicaid Services). *Bright Futures* has also become widely embraced by State Medicaid programs, which have integrated the recommendations into covered services for infants, children, and adolescents. AAP has spearheaded implementation efforts and promoted the use of *Bright Futures* in clinical health systems, public health settings, school resource centers, and elsewhere, and regularly facilitates updating *Bright Futures*. During the discussion and drafting of the Patient Protection and Affordable Care Act ("ACA"), AAP supported the provision which makes coverage for pediatric preventive care and screening mandatory without cost sharing.

AAP also collaborates with the Centers for Disease Control and Prevention ("CDC"), the Advisory Committee on Immunization Practices, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and American College of Nurse-Midwives to produce the annual immunization schedules (recommended immunizations) for children from birth to age eighteen. AAP also supported making coverage for vaccinations on the Immunization Schedule mandatory without cost sharing. *See* 42 U.S.C. § 300gg-13(a)(2). AAP believes, and research supports, that seamless access to vaccination is important for pediatric public health. Since the ACA was passed, the Department of Health and Human Services (HHS) has not implemented regulations exempting employers from

providing coverage for pediatric care or immunizations under 42 U.S.C. § 300gg-13(a)(2)-(3).

SUMMARY OF ARGUMENT

Vaccination is a vital part of this nation's public health system, and it is especially important for children. A routine schedule of vaccines is recommended by the Centers for Disease Control and Prevention ("CDC") for children, and the ACA requires insurance companies to cover such vaccines without cost sharing. 42 U.S.C. § 300gg-13(a)(2). Like employers who object to contraception, some individuals have religious and moral objections to vaccinations, including vaccinations that are included in the CDC's Immunization Schedules. While the exemptions before the Court in this case only apply to employers who object to providing coverage for certain forms of contraception, Petitioners' reasoning could reach far more broadly.[2]

Since 2013, the government has allowed certain employers with religious objections to exclude contraception from their plans while requiring a third party—the insurer or third-party administrator—to provide that coverage to women directly at no cost to the objecting employer. The Court extended this accommodation, which required employers to submit a self-certification form in order to opt out of the requirement, to closely-held for-profit entities in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), holding that it represented a less restrictive means of

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[2] Throughout this brief, Amicus uses the term "Petitioners" to refer to the Petitioners in both cases before this court, Nos. 19-431 and 19-454. In places, Amicus refers to the "Agencies" to mean the executive officers and/or agencies who are petitioners in No. 19-454.

applying the coverage mandate to such employers and stating the accommodation "[did] not impinge on the petitioners' religious beliefs." *Id.* at 731. Other employers then challenged this accommodation directly, arguing that the act of self-certification itself violated their religious beliefs, and in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), this Court remanded the issue to the Agencies to negotiate a solution. *Id.* at 1560.

In 2017, the Departments of Health and Human Services, Labor, and the Treasury issued interim final rules, without notice and comment, that create broad religious and moral exemptions from the contraceptive care guarantee. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017). In November 2018, the agencies replaced these rules with nearly identical "final rules." *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018).[3] Under all of these rules, the mandatory contraceptive coverage required by the ACA is no longer mandatory for those who work for an employer with a religious or moral objection to that coverage. In other words, the

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[3] Throughout this brief, Amicus uses the term "rules," to refer to both the 2017 interim final rules and the 2018 final rules, since they are, for all material aspects, the same.

accommodation, which was previously upheld in *Hobby Lobby*, is no longer required for all employers.

The Agencies' rules go far beyond the accommodation reviewed in *Hobby Lobby* or *Zubik*. Under the new rules, any private employer could refuse to provide coverage through its existing health plan based on a religious or moral opposition to contraceptive coverage, and the employer can refuse to allow its employees to receive contraception without cost sharing from the plan administrator. If this Court rules in Petitioners' favor and allows these rules to remain in place, future objectors could likely seek to expand the rules to apply to vaccinations, and prevent children from obtaining critical, life-saving preventive care.

This was true at the time this Court decided *Hobby Lobby* and *Zubik*, but it is even more true today. If employers with religious or moral opposition to vaccinations were to seek exemptions under the Agencies' rules, some untold number of children would lack seamless access to critical medical care. This would not only put the lives of those children at risk, but would increase the risk of many others in the community. Maintaining herd immunity—the percentage of people in the community who need to be vaccinated to prevent widespread transmission of a disease—is vital to keeping the public safe. The current global pandemic caused by the novel coronavirus—a disease for which vaccines are under development but not currently available—only underscores the importance of preventing the spread of infectious disease. When even a small portion of the population lacks access to vaccinations, everyone is put at risk. This Court can—and should—prevent this threat to public health and affirm the Third Circuit's opinion.

ARGUMENT

I. The Court's Approval of the Agencies' Sweeping Religious and Moral Exemptions Could Impede Access to Life-Saving Healthcare for Children.

A. Many Individuals Have Religious or Moral Objections to Vaccinations that Are Essential for Children's Health.

Vaccines are vital to public health. This is particularly true for children, for whom a routine schedule of vaccines is recommended by the CDC from birth to age eighteen.[4] Specifically, the CDC recommends that children receive all immunizations listed on the CDC's Immunization Schedules, which the AAP co-authors. 29 C.F.R. § 2590.715–2713; 45 C.F.R. § 147.130. The ACA requires insurance providers to cover the vaccines listed in the Immunization Schedules without cost sharing. 42 U.S.C. § 300gg-13(a)(2).

Vaccines are critical in protecting Americans from infectious diseases. Indeed, public health studies routinely find significant reductions in illness and death attributed to vaccine-preventable disease from routine childhood immunization in line with medical recommendations. For instance, one peer-reviewed study estimated that the use of seven childhood

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[4] *See* Ctrs. for Disease Control & Prevention, Immunization Schedules, *Table 1. Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2020*, https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (last visited Mar. 30, 2020).

vaccinations that have long been recommended for routine administration prevents an estimated 33,000 deaths and 14 million cases of disease for the children born in the United States in a single year.[5] For individuals born in the United States between 1994 and 2013, "vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes."[6] And healthy children need vaccination so that the larger population can maintain "herd immunity" (also called "community immunity"), which is essential for preventing the spread of infectious and sometimes deadly diseases to children or adults who—for legitimate medical reasons—cannot receive vaccines.[7]

But despite the importance of vaccines to children's health—and public health overall—some individuals have religious or moral objections to their use. Many have objections to vaccinations that are currently on the CDC's Immunization Schedules.[8] For example, some object to vaccines for chicken pox, hepatitis A, hepatitis

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[5] Sandra W. Roush & Trudy V. Murphy, *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 JAMA 2155, 2160 (2007).

[6] Fangjun Zhou, et al., *Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States, 2001*, 159 Arch Pediatric Adolescent Med. 1136 (2005).

[7] *See* Paul Fine et al., *"Herd Immunity": A Rough Guide*, 52 Clinical Infectious Diseases 911 (2011), https://academic.oup.com/cid/article/52/7/911/299077.

[8] *See, e.g.*, Mathew D. Staver, *Compulsory Vaccinations Threaten Religious Freedom*, Liberty Counsel (2007), https://www.lc.org/memo_vaccination.pdf.

B, polio, and MMR (measles, mumps, and rubella) because those vaccines have an attenuated connection to fetal tissue research conducted in the 1960s.[9] Indeed, in 2015 a mother sought (and received) an exemption from New York City's requirement that her child receive the MMR vaccine based on her professed belief that—because of the connection to fetal-tissue research—using the vaccine violated the tenets of the Russian Orthodox faith.[10]

Similarly, in 2014, a paramedic student brought suit to challenge his training program's vaccination requirement because vaccines derived from fetal tissue allegedly impinged on his Christian beliefs.[11] And the

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[9] Richard K. Zimmerman, *Ethical Analyses of Vaccines Grown in Human Cell Strains Derived from Abortion: Arguments and Internet Search*, 22 Vaccine 4238 (2004). To be clear, individual doses of these vaccines are not produced using fetal tissue, nor do they contain fetal tissue. Rather, the vaccines are grown in human cell cultures developed from two cell lines that trace back to two fetuses, both of which were legally aborted for unrelated medical reasons in the early 1960s. *See* Children's Hospital of Philadelphia, *Vaccine Ingredients – Fetal Tissues*, https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients/fetal-tissues#.VrPwcLIrK70 (last visited Apr. 3, 2020).

[10] Jennifer Gerson Uffalussy, *Anti-Vax, Meet Anti-Abortion: Woman Uses Fetal Tissue Link to Skirt Vaccine Law in NYC*, Yahoo! Health (Sept. 2, 2015), *archived at* https://perma.cc/3VYW-EG49.

[11] Compl., *George v. Kankakee Cmty. College*, No. 2:14-cv-02160 (C.D. Ill. July 3, 2014), ECF No. 1-1. The student brought a challenge under RFRA, but the district court dismissed his claim on the ground that RFRA does not apply to state action. *George v. Kankakee Cmty. College*, No. 2:14-cv-02160, 2014 WL 6434152, at *4–5 (C.D. Ill. Nov. 17, 2014).

Catholic Church's Sacred Congregation of the Doctrine of the Faith has proclaimed that, while parents may vaccinate their children with vaccines derived from fetal cell lines where there is no alternative and when necessary to protect against serious disease, the production, marketing, and use of such vaccines is considered to be "passive material cooperation" with evil.[12] The Congregation has further proclaimed that followers may "oppose by all means" those vaccines which do not yet have "morally acceptable alternatives," and abstain from using such vaccines if doing so can be done without causing significant risks to health.[13] And in fact, some Catholic groups have done just that, by actively encouraging parents to refuse objectionable vaccines.[14]

The vaccine against the human papillomavirus (HPV) is equally controversial. Certain strains of HPV can cause a variety of cancers, most notably cervical cancer.[15]

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[12] Pontifica Academia Pro Vita, *Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Foetuses* (June 9, 2005), https://www.immunize.org/talking-about-vaccines/vatican document.htm; *Vatican Condemns Vaccines Derived from Aborted Fetuses, Puts Onus on Pharma*, Catholic News Agency (July 19, 2005), *archived at* https://perma.cc/V479-UM9A (reporting that the "Vatican also supports parents who refuse to use the vaccines").

[13] Catholic News Agency, *supra* note 12.

[14] *See* Fr. Phil Wolfe, *The Morality of Using Vaccines Derived from Fetal Tissue Cultures: A Few Considerations*, Children of God for Life (2015), https://cogforlife.org/fr-phil-wolfe/ (arguing that Catholics cannot "disclaim the origin of this vaccine," which is "evil").

[15] Ctrs. for Disease Control & Prevention, *HPV Vaccine Information for Clinicians – Fact Sheet* (last reviewed July 8, 2012),

Each year, approximately 11,000 women in the United States are diagnosed with cervical cancer—and almost half that number die from it.[16] Because HPV is often transmitted through sexual contact, and because the HPV vaccine is most effective when administered before the patient comes in contact with the virus, medical experts and organizations—including the AAP—recommend that the HPV vaccine be administered at 11 or 12 years of age.[17] But because HPV can be transmitted sexually, some religious objectors steadfastly oppose the vaccine on the basis that it allegedly encourages teens to engage in premarital sex, and that the correct way to limit transmission is through abstinence.[18]

Objections are not limited to the HPV vaccine or to vaccines derived from fetal tissue research. Some religious adherents object to vaccines that contain bovine or porcine extracts, or blood fragments.[19] Still others object to vaccines generally because they believe

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archived at https://perma.cc/9ANQ-FWWK.

[16] *Id.*

[17] *Id.*; American Academy of Pediatrics Committee on Infectious Diseases, *Recommended Childhood and Adolescent Immunization Schedule—United States, 2016*, 137 Pediatrics, Mar. 2016, http://pediatrics.aappublications.org/content/pediatrics/early/2016/01/28/peds.2015-4531.full.pdf.

[18] Joseph E. Balog, *The Moral Justification for a Compulsory Human Papillomavirus Vaccination Program*, 99 Am. J. Pub. Health 616, 617 (2009).

[19] Tara M. Hoesli et al., *Effects of Religious and Personal Beliefs on Medication Regimen Design*, 34 Orthopedics 292, 292–95 (2011).

that vaccines defile the body with foreign substances, like live viruses.[20]

Moral and philosophical objections to vaccination, a broad umbrella category often known as "personal belief objections," have also become more common. Despite the fact that vaccines are regularly proven safe, many parents adhere to strict anti-vaccination beliefs, regardless of religious affiliation. For example, many parents oppose vaccinations as a matter of personal liberty,[21] or because they do not trust the government

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[20] *Id.* Some religious adherents also object to other medical services that are crucial for comprehensive pediatric health care. For example, some followers of Judaism and Islam object to the ingestion of all medications containing gelatin—which is manufactured using tissue from animals and is a common inactive ingredient in medication, particularly in "capsule shells." *Id.*; Bharat Vissamsetti et al., *Inadvertent Prescription of Gelatin-Containing Oral Medication: Its Acceptability to Patients*, 88 Postgrad. Med. J., 499 (2012). Jehovah's Witnesses prohibit the introduction of blood and its components into their bodies, and thus object to blood and plasma transfusions—even when a transfusion is necessary to save a child's life. J. Lowell Dixon & M. Gene Smalley, *Jehovah's Witnesses: The Surgical/Ethical Challenge*, 246 JAMA 2471, 2471–72 (1981). Christian Scientists consider most medicines and procedures—aside from "mechanical" procedures, like setting bones—to be incompatible with their religious beliefs. *The Christian Science Tradition: Religious Beliefs and Healthcare Decisions*, Park Ridge Ctr. 2–4 (Deborah Abbott ed., 2002), https://www.advocatehealth.com/assets/documents/faith/christian_science_final2.pdf. And the Church of Scientology opposes all psychiatric care, especially for children—and even for severe psychotic disorders like schizophrenia. *See* Alisa Ulferts, *Scientologists Push Mental Health Law*, Tampa Bay Times (Apr. 9, 2005), *archived at* https://perma.cc/RX8U-F4EG.

[21] Brittney Martin, *Texas Anti-Vaxxers Fear Mandatory COVID-19 Vaccines More Than the Virus Itself*, Texas Monthly (Mar. 18, 2020),

agencies that approve vaccines.[22] Others have scientifically unfounded beliefs that vaccines are dangerous, cause autism, asthma, or overload their children's immune systems.[23] Many parents who oppose vaccination believe their children will be healthier after contracting certain diseases, because their natural immunity is better than immunity acquired through a vaccine.[24] Still others believe vaccines are made with toxic substances and cause severe allergic reactions.[25] Overall, in the last ten years, the number of parents claiming personal belief exemptions to vaccination for school-aged children has increased in a majority of the states that allowed such philosophical exemptions.[26] For

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https://www.texasmonthly.com/news/texas-anti-vaxxers-fear-mandatory-coronavirus-vaccines/.

[22] Jennifer Reich, *I've Talked To Dozens Of Parents About Why They Don't Vaccinate. Here's What They Told Me.*, Vox (June 13, 2019), https://www.vox.com/first-person/2019/5/8/18535944/jessica-biel-measles-2019-outbreak-anti-vax.

[23] *See* Alana C. Ju, *What I Learned from the Antivaccine Movement*, 144 Pediatrics, Oct. 2019, at 2, http://pediatrics.aappublications.org/content/144/4/e20192384. A recent Gallup poll found that 10% of Americans currently believe that vaccines cause autism, up from only 6% in 2015. RJ Reinhart, *Fewer in U.S. Continue to See Vaccines as Important*, Gallup (Jan. 14, 2020), https://news.gallup.com/poll/276929/fewer-continue-vaccines-important.aspx.

[24] Chephra McKee & Kristin Bohannon, *Exploring the Reasons Behind Parental Refusal of Vaccines*, 21 J. Pediatric Pharmacology & Therapeutics 104 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4869767/.

[25] *Id.*

[26] Jacqueline K. Olive, et al., *The State of the Antivaccine Movement in the United States: A Focused Examination of Nonmedical Exemptions in States and Counties*, 15 PLoS Med, June 12, 2018, at

example, between 2007 and 2013, the percentage of kindergarteners in California who received personal belief exemptions doubled—from 1.54% to 3.06%[27]

Of course, the First Amendment protects the sincerely held beliefs of parents to refuse certain medical care to their children that does not comport with their religious beliefs or moral values. But those choices are not implicated by this case. Rather, the rationale in the Agencies' rules, if applied broadly, would allow nearly any *business owner* with a religious objection to, or moral qualm with, vaccinations, to opt out of providing coverage for vaccines for their *employees' children* through its health plan. This effectively denies access to life-saving treatments for children whose parents do not share those same beliefs.

B. Religious and Moral Objections to Vaccinations Have Become More Common, and Dangerous, in Recent Years.

Since this Court decided *Hobby Lobby* in 2014, religious and moral objections to vaccinations for children have become more common and have put more lives at risk. Increasing opposition to the MMR vaccine in particular has resulted in a resurgence of measles outbreaks across the country. Because measles is especially contagious, the vaccine rate needed to achieve

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1, https://doi.org/10.1371/journal.pmed.1002578.

[27] Y. Tony Yang, et al., *Sociodemographic Predictors of Vaccination Exemptions on the Basis of Personal Belief in California*, 106 Am. J. Pub. Health 172 (Jan. 2016).

effective herd immunity is close to 95 percent.[28] A dip of only a few percentage points in the number of vaccinated children can leave the community vulnerable to an outbreak.[29]

Indeed, a 2014 outbreak at the Disneyland amusement park in California vividly shows what happens when fewer children receive vaccines and "herd immunity" is compromised. Between December 2014 and January 2015, 39 people—many of them children—were infected with measles after visiting Disneyland.[30] The infection rapidly spread from those individuals to others, and within weeks infected at least 125 people across several states.[31] Of those victims, 49 were unvaccinated, and 12 were infants too young to be vaccinated.[32] Although the source of the original infection is unknown, it is believed to have been a single individual who, after contracting the virus overseas,

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[28] Jan Hoffman, *How Anti-Vaccine Sentiment Took Hold In the United States*, N.Y. Times (Sept. 23, 2019), https://www.nytimes.com/2019/09/23/health/anti-vaccination-movement-us.html.

[29] A recent study found that a five percent decline in MMR vaccine coverage in the US "would result in an estimated 3-fold increase in measles cases for children aged 2 to 11 years nationally every year." *See* Nathan C. Lo & Peter J. Hotez, *Public Health and Economic Consequences of Vaccine Hesitancy for Measles in the United States*, 171 JAMA Pediatrics 887, 890 (2017).

[30] Jennifer Zipprich et al., *Measles Outbreak – California, December 2014 – February 2015*, 64 CDC Morbidity & Mortality Weekly Report 153 (Feb. 20, 2015), https://www.cdc.gov/mmwr/pdf/wk/mm6406.pdf.

[31] *Id.*

[32] *Id.*

visited Disneyland and transmitted the infection to other visitors.[33] The Disneyland outbreak shows the importance of ensuring maximal immunization coverage across the population: Without comprehensive protection, one infected individual can sicken hundreds—or more.[34]

In 2018, a measles outbreak in New York City resulted in 600 confirmed cases, and another outbreak began the next day in a neighboring county, causing more than 300 cases.[35] In 2019, there were 1,282 confirmed cases of measles in the U.S.—the highest number since 1992.[36] A large percentage of these cases occurred in communities with clusters of unvaccinated individuals.[37] The World Health Organization ("WHO") listed "vaccine hesitancy"—"the reluctance or refusal to vaccinate despite the availability of vaccines"—as one of

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[33] Nicholas Bakalar, *What Travelers Need to Know About Measles*, N.Y. Times (Feb. 3, 2015), http://www.nytimes.com/2015/02/03/travel/what-travelers-need-to-know-about-measles.html?ref=topics.

[34] Measles in particular is one of the most infectious viruses known to medicine—it can remain suspended in the air for up to two hours, and can infect a person entering a room even after an infectious person has left. Paul A. Gastañaduy & James L. Goodson, *Travel-Related Infectious Diseases: Measles (Rubeola)*, Ctrs. for Disease Control & Prevention, http://wwwnc.cdc.gov/travel/yellowbook/2016/infectious-diseases-related-to-travel/measles-rubeola (last visited Mar. 30, 2020).

[35] *Id.*

[36] Ctrs. for Disease Control & Prevention, *Measles Cases and Outbreaks*, https://www.cdc.gov/measles/cases-outbreaks.html (last visited Mar. 30, 2020).

[37] *Id.*

its top ten threats to global health in 2019.[38] And due to falling vaccination rates, there was a "reasonable chance" that the U.S. would lose its measles elimination status from the WHO in 2019.[39]

This issue is not limited to the MMR vaccine. The CDC found that for the 2017-2018 school year, overall vaccination rates for kindergarteners nationwide had dropped to 94 percent—the third year in a row to show a decline.[40] In Colorado, a state that allows both religious and philosophical exemptions, the vaccination rate for kindergarteners is only 87.4%; Idaho's is 89.5%.[41]

Indeed, non-medical exemptions are specifically linked to lower vaccination rates. For example, one study examined the rise in pertussis (whooping cough)

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[38] World Health Organization, *Ten Threats to Global Health in 2019*, https://www.who.int/news-room/feature-stories/ten-threats-to-global-health-in-2019 (last visited Mar. 20, 2020).

[39] Elizabeth Cohen, *The U.S. Eliminated Measles in 2000. The Current Outbreak Could Change That*, CNN (Sept. 3, 2019), https://www.cnn.com/2019/08/28/health/us-measles-elimination-status-in-jeopardy/index.html.

[40] Jenelle L. Mellerson, *Vaccination Coverage for Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2017–18 School Year*, 67 CDC Morbidity & Mortality Weekly Report 1115 (Oct. 12, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6740-H.pdf; *see also* Hoffman, *supra* note 28 ("Seven states reported rates for the M.M.R. vaccine that were far lower for kindergartners, including Kansas at 89.5 percent; New Hampshire, 92.4 percent; the District of Columbia, 81.3 percent.").

[41] Ctrs. for Disease Control & Prevention, *2009-10 through 2018-19 School Year Vaccination Coverage Trend Report*, https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/data-reports/coverage-trend/index.html (last visited Mar. 20, 2020).

cases in the United States and found that outbreaks of the disease, which is covered by the CDC-recommended DTaP vaccine for children under seven, were clustered in areas that had higher rates of non-medical vaccine exemptions for kindergarteners.[42]

As recently as 2019, 44 states allowed parents with religious objections to vaccines to opt out of regulations requiring vaccination before their children attend public school; 15 of those states also allowed personal or moral objections. Five states (California, New York, Mississippi, West Virginia, and Maine) have no non-medical exemptions for vaccination.[43] California revised its laws in 2016 to no longer allow religious exemptions, citing public health concerns.[44] In 2019, New York ended its practice of allowing parents to get an exemption from vaccination requirements because of religious beliefs; the state now only allows medical exemptions.[45]

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[42] Carlin Aloe, Martin Kulldorff, & Barry R. Bloom, *Geospatial Analysis of Nonmedical Vaccine Exemptions and Pertussis Outbreaks in the United States*, 114 Proc. Nat'l Acad. Sci. 7101, 7104 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5502604/pdf/pnas.201700240.pdf.

[43] Pew Research Ctr., *Most States Allow Religious Exemptions for Childhood Vaccines* (June 28, 2019), https://www.pewresearch.org/fact-tank/2019/06/28/nearly-all-states-allow-religious-exemptions-for-vaccinations/ft_19-06-28_statevaccine_640px/.

[44] Robert A. Bednarczyk, et al., Current Landscape of Nonmedical Vaccination Exemptions in the United States: Impact of Policy Changes, 18 Expert Rev. Vaccines 175, 183 (2019).

[45] Sharon Otterman, *Get Vaccinated or Leave School: 26,000 N.Y. Children Face a Choice*, N.Y. Times (Sept. 3, 2019), https://www.nytimes.com/2019/09/03/nyregion/measles-vaccine-

The current global pandemic caused by the novel coronavirus only underscores the importance of seamless access to vaccination. Experts currently understand the novel coronavirus to be twice as contagious as the flu and significantly more deadly.[46] Yet, some are already expressing opposition to a coronavirus vaccine.[47] When a vaccine is ultimately developed, its widespread adoption will be critical to protecting society. Congress, cognizant of this important fact, added the COVID-19 vaccination to the list of preventative services that must be provided without cost sharing under § 300gg-13(a) in its most recent legislation responding to the pandemic. *See* Coronavirus Aid, Relief, and Economic Security Act, § 3203, Pub. Law No. 116-136, 134 Stat. 281, 367-68 (2020).

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exemptions-ny.html.

[46] *See* World Health Organization, *Q&A: Similarities and differences – COVID-19 and influenza* (Mar. 17, 2020), https://www.who.int/news-room/q-a-detail/q-a-similarities-and-differences-covid-19-and-influenza; Adam J. Kucharski et al., *Early Dynamics Of Transmission And Control Of COVID-19: A Mathematical Modelling Study*, Lancet (Mar. 11, 2020), https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30144-4/fulltext; Ying Liu et al., *The Reproductive Number Of COVID-19 Is Higher Compared To SARS Coronavirus*, 27 J. Travel Med. (Mar. 2020), https://academic.oup. com/jtm/article/27/2/taaa021/5735319.

[47] Martin, *supra* note 21.

C. If This Court Accepts Petitioners' Arguments as to Contraceptive Coverage, Others Will Likely Seek to Expand the Reasoning to Vaccines.

Reversing in this case and sanctioning the Agencies' expansive interpretation of RFRA would likely invite countless more objections to coverage for essential medical care. While the current regulations apply only to the ACA's contraceptive mandate, Petitioners' interpretation of RFRA would likely apply as well to religious objections to other medical treatments—including vaccinations. According to Petitioners, there is a substantial burden on religious employers from their association with a plan that covers services to which they object, even if the employers do not pay for such coverage. *See* Pet. Br. in 19-454 at 24; Pet. Br. in 19-431 at 23. Petitioners' reasoning thus invites an identical exemption for religious objections to vaccinations, since the argument is focused on the adherent's religious beliefs, not the particular medical care being delivered.

If the Court upholds the Agencies' rules, an employer may totally exempt itself from the contraceptive-coverage requirement, and need not allow the plan administrator to arrange for alternate coverage. Presumably, an employer who objects would seek to do the same for the immunization-coverage requirement, and the same outcome would follow. While there has not *yet* been a flood of employers seeking exemptions to the ACA's immunization-coverage requirement, the threat is no less real. If this Court decides in favor of Petitioners, it may encourage employers to opt out of other coverage from their health plans—including vaccinations.

In fact, religious objections to all sorts of laws proliferated in the wake of this Court's decision in *Hobby Lobby*. For example, when Pacific Lutheran University's requested a religious-based exemption from national labor laws, it relied on this Court's decision in *Hobby Lobby* as precedent.[48] Similarly, a member of the Fundamentalist Church of the Latter Day Saints sought—and won—a religious exemption that allowed him to avoid testifying in a federal investigation into the church's alleged violations of child-labor laws. *Perez v. Paragon Contractors, Corp.*, No. 2:13CV00281-DS, 2014 WL 4628572 (D. Utah Sept. 11, 2014). In light of these attempts to seek religious exemptions from generally applicable laws, it is likely that religious adherents and moral objectors will have similar objections to the ACA's immunization coverage requirement.

Likewise, the Agencies' justification for the exemption to contraceptive coverage based on moral grounds would similarly be difficult to cabin to contraceptive coverage alone. The rules explain that this

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[48] *See* Notice of Supplemental Authority and Supplemental Brief of *Amicus Curiae* National Right to Work Legal Defense and Education Foundation, Inc. Regarding *Burwell v. Hobby Lobby Store, Inc.*, at 5, Pac. Lutheran Univ. and Serv. Emps. Int'l Union, Local 925, No. 19-RC-102521 (N.L.R.B. Sept. 24, 2014) (arguing that, "[l]ike the substantial burden found in Hobby Lobby, the [National Labor Relations] Board forces the University to violate its conscience by bargaining in good faith on promoting the Union's pro-abortion agenda through the collective bargaining agreement"; and that "[j]ust as all the exceptions to the HHS mandate demonstrated that the least restrictive alternative was not in place, so the massive exceptions to collective bargaining under the NLRA show that mandating collective bargaining for the University is not the least restrictive alternative").

exemption is designed "to bring the Mandate into conformity with Congress's long history of providing for or supporting conscience protection in the regulation of healthcare issues."[49] 82 Fed. Reg. at 47,844; *see also id.* at 47,846 (describing the protection for conscientious objectors to the draft); *id.* at 47,847 (describing state law protections for moral objections to participation in abortion or sterilization procedures); 83 Fed. Reg. at 57,559. This reasoning invites an identical exemption for those with moral objections to vaccinations, with no obvious limiting principle.

The Agencies contend that the number of employers who will seek to use the moral exemption to contraceptive coverage is small. 82 Fed. Reg. at 47,848. Putting aside whether this is true for those opposed to contraception, recent experience suggests that opposition to vaccination based on moral and religious beliefs is only increasing. *See supra* at 13-15. Indeed, there is ample evidence at the state level that a decision in favor of Petitioners will invite an increase in desired exemptions to the vaccine coverage requirement. As documented above, the number of parents seeking exemptions from state laws requiring vaccination has only grown in the time since this Court decided *Hobby Lobby*. *See supra* at 15-18. Importantly, the ease of getting an exemption increases its use. In states where the personal belief exemption is moderately more difficult to obtain (for example, if parents need to have a

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[49] The Agencies rely on this history despite the fact that Congress explicitly chose not to include such an exemption in the ACA, *see* Resp't Br. at 33; 158 Cong. Rec. 2621-34 (2012), and no party argues RFRA authorizes the moral exemption.

form notarized, draft their own letter, or have the form re-authorized each year), the percent of students with vaccine exemptions based on personal belief is lower than in states with looser requirements.[50] There is reason to expect that the easier it is for employers to opt out of vaccination coverage, the more likely it is that they will do so.

D. The Agencies' Rules Will Increase Costs and Administrative Burdens on Families, Making It Harder for Them to Obtain Life-Saving Preventive Care for Their Children.

If the Court rules in favor of Petitioners and others successfully use the same rationale to justify vaccine exemptions, it will be significantly harder for affected families to obtain immunization coverage for their children. This will lead to lower rates of immunizations and increased incidence of potentially deadly diseases.

Indeed, each of the possible alternatives that the Agencies suggest for obtaining contraceptive coverage outside of the employer-sponsored plan would impose heavy administrative burdens and costs on families. For example, the Agencies suggest that employees or their dependents find and purchase an individual health plan on an insurance exchange, but that would require significant investments of time and research to select the appropriate plan—assuming a comparable individual plan even exists, which is never guaranteed. *See* 82 Fed. Reg. at 47,807. And it is extremely unlikely that many parents would expend that time and money—and give up

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[50] *See* Bednarczyk, et al., *supra* note 44.

generous premium subsidies offered by employers—to purchase an exchange plan that covers only a few additional services. Given the eligibility criteria for advanced premium tax credits on the individual market, it is unlikely that individuals and families facing such a choice would even qualify for financial assistance, since the availability of affordable employer-sponsored coverage is generally a disqualifying factor. In other words, many families would be faced with a difficult choice: accept a health plan with critical gaps in covered services that prevent them from seeking the care they need or purchase unsubsidized coverage at great expense to have access to services that Congress intended be available to all. [51]

The Agencies also suggest that federal, state, and local programs will provide an adequate substitute for women seeking coverage for contraception. 82 Fed. Reg. at 47,803. Although government benefits like the federal Vaccines for Children ("VFC") program are important components of a comprehensive immunization strategy, they are no substitute for private health insurance. Indeed, studies show that VFC-eligible children are vaccinated at a much lower rate than privately insured children due to various barriers to access.[52] For example, although children whose health plans do not cover vaccines can obtain them through VFC, they sometimes

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[51] Additionally, tax credits for insurance premiums are generally *not* available to an employee's family if his or her employer offers individual (i.e., non-family) coverage that meets an affordability standard—even if the employee would otherwise qualify for a subsidy based on income. *See* 26 C.F.R. § 1.36B-2.

[52] Philip J. Smith et al., *Vaccination Coverage Among U.S. Children Aged 19–35 Months Entitled by the Vaccines for Children Program, 2009*, 126 Pub. Health Rep. 109 (2011).

must travel to certain federally qualified health centers ("FQHCs") or rural health clinics ("RHCs") in order to do so. 42 U.S.C. § 1396s(b)(2)(A)(iii). Thus, parents participating in VFC cannot always have their children vaccinated during an appointment with their primary health care provider, and instead have to make a separate trip to a different facility (and fill out additional forms) to obtain critical vaccines. Studies show that these barriers to access, and in particular the need to make special trips and arrangements to obtain vaccines, make it significantly less likely that children will be vaccinated.[53] By contrast, when a parent's employer-sponsored health plan includes immunization coverage, families face minimal or no barriers to obtaining vaccinations for their children, and children are vaccinated at a much higher rate.[54]

If religious and other objectors are allowed to place additional burdens on families that need comprehensive immunization coverage, then vaccination rates will fall and the spread of infectious (and sometimes deadly) diseases—potentially including COVID-19, the disease caused by the novel coronavirus—will rise. Even a minor increase in either administrative or financial burdens can significantly deter patients from receiving important medical care. For example, a 2010 study found that patients who had to opt in to a free vaccination program

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[53] Philip J. Smith et al., *The Association Between Having a Medical Home and Vaccination Coverage Among Children Eligible for the Vaccines for Children Program*, 116 Pediatrics 130 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3113436/pdf/phr126s201.09.pdf.

[54] Smith et al., *Vaccination Coverage*, *supra* note 52, at 137.

were 36% less likely to receive the vaccine compared to patients who were automatically enrolled, suggesting that even minor logistical barriers will result in fewer families signing up for immunization coverage and vaccinating their children.[55] Other studies bear this out, showing that when bureaucratic obstacles and other factors make vaccinations inconvenient, patients are less likely to obtain critical vaccines.[56] Similarly, the CDC has found that children without private health insurance, as well as those living below the poverty level and in more rural areas, have the lowest levels of vaccine coverage.[57]

Because maximal immunization rates and "herd immunity" are necessary for preventing the spread of potentially deadly childhood diseases, it is essential that access to vaccines be as convenient and easy for families as possible. Yet, upholding the Agencies' rules could have the opposite effect. Upholding exemptions to contraceptive coverage could lead to exemptions for vaccines. Lower vaccination rates would lead to disastrous consequences for children's health—and the health of the nation. Vaccination coverage must continue

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[55] Gretchen B. Chapman et al., Research Letter: *Opting In vs Opting Out of Influenza Vaccination*, 304 JAMA 43, 43–44 (2010).

[56] Felicity T. Cutts et al., *Causes of Low Preschool Immunization Coverage in the United States*, 13 Ann. Rev. Pub. Health 385, 389 (1992), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3113436/pdf/phr126s20109.pdf.

[57] *Confronting a Growing Public Health Threat: Measles Outbreaks in the U.S: Hearing Before the Subcomm. on Oversight and Investigations Members and Staff of the H. Comm. On Energy and Commerce*, 116th Cong. (2019), https://www.cdc.gov/washington/testimony/2019/t20190227.htm (statement of Dr. Nancy Messonnier, Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention).

uninterrupted and without additional administrative or economic burdens that would hinder families' access to that vital preventive care.

CONCLUSION

For the foregoing reasons, as well as those in the Respondents' brief, Amicus respectfully requests that this Court affirm the decision of the court below.

Respectfully submitted,

DEVI M. RAO
Counsel of Record
JENNER & BLOCK LLP
1099 NEW YORK AVENUE NW
WASHINGTON, DC 20001
(202) 637 6390
drao@jenner.com

Counsel for Amicus Curiae

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