UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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CENTRAL RABBINICAL CONGRESS OF THE USA & CANADA; AGUDATH ISRAEL OF AMERICA; INTERNATIONAL BRIS ASSOCIATION; RABBI SAMUEL BLUM; RABBI AHARON LEIMAN; and RABBI SHLOIME EICHENSTEIN,

Plaintiffs,

- against -

NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE; NEW YORK CITY BOARD OF HEALTH; and DR. THOMAS FARLEY, in his official capacity as Commissioner of the New York City Department of Health & Mental Hygiene,

Defendants.
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MEMORANDUM AND ORDER

12 Civ. 7590 (NRB)

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

I. Introduction

On September 13, 2012, the New York City Board of Health (the "Board of Health" or the "Board") voted unanimously to amend Article 181 of the New York City Health Code by adding a new section 181.21. Section 181.21 prohibits any person from performing a circumcision that involves direct oral suction without first obtaining the written consent of one of the infant's parents. The consent may be recorded on either a form prepared by the New York City Department of Health and Mental Hygiene ("DOHMH" or the "Department") or a different form that

contains specific mandatory language warning parents that direct oral suction will be performed and that the Department advises against it because it exposes children to the risk of herpes simplex virus infection, which may result in brain damage or death. As defendants acknowledge, the only instance they are aware of in which direct oral suction during circumcision occurs, and therefore the only activity the Board of Health expected the regulation realistically to apply to, is "metzitzah b'peh" -- a practice among some observant Jews in which a ritual circumciser, or mohel, places his mouth on a newly circumcised penis to draw blood away from the wound.

The regulation's Notice of Adoption was published in The City Record on September 21, 2012, and the regulation was scheduled to enter into force thirty days later, on October 21, 2012. However, on October 11, 2012, plaintiffs, several mohels and organizations representing mohels, filed suit in this Court against the Board of Health, DOHMH, and the Commissioner of DOHMH, Dr. Thomas Farley, seeking declaratory and injunctive relief barring enforcement of section 181.21. Plaintiffs argue that the regulation compels speech in violation of the First Amendment and violates their rights to free exercise of religion under the First Amendment and article I, section 3 of the New York State Constitution.

In lieu of litigating a temporary restraining order, the parties stipulated to a stay of enforcement of section 181.21 through the date of oral argument on plaintiffs' motion for a preliminary injunction. Plaintiffs filed their motion for a preliminary injunction on October 16, 2012; defendants filed their opposition on November 15, 2012; and plaintiffs filed their reply on November 30, 2012. An amicus curiae submission in opposition to plaintiffs' motion was filed on November 20, 2012, by the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, the American Academy of Pediatrics, and the American Sexually Transmitted Diseases Association. On December 18, 2012, the Court heard oral argument, at the conclusion of which we continued the stay of enforcement until such time as we ruled on plaintiffs' motion for a preliminary injunction.

For the reasons stated below, plaintiffs' motion for a preliminary injunction is denied.

II. Background

A. The Regulation

In its final form, section 181.21 reads as follows:

> § 181.21 Consent for direct oral suction as part of a circumcision.
>
> (a) Direct oral suction means contact between the mouth of a person performing or assisting in the performance of a circumcision and an infant's circumcised penis.

> (b) Written consent required. A person may not perform a circumcision that involves direct oral suction on an infant under one year of age, without obtaining, prior to the circumcision, the written signed and dated consent of a parent or legal guardian of the infant being circumcised using a form provided by the Department or a form which shall be labeled "Consent to perform oral suction during circumcision," and which at a minimum shall include the infant's date of birth, the full printed name of the infant's parent(s), the name of the individual performing the circumcision and the following statement: "I understand that direct oral suction will be performed on my child and that the New York City Department of Health and Mental Hygiene advises parents that direct oral suction should not be performed because it exposes an infant to the risk of transmission of herpes simplex virus infection, which may result in brain damage or death."
>
> (c) Retention of consent forms. The person performing the circumcision must give the parent or legal guardian a copy of the signed consent form and retain the original for one year from the date of the circumcision, making it available for inspection if requested by the Department.

Notice of Adoption of an Amendment to Article 181 of the New York City Health Code, The City Record, Sept. 21, 2012, at 2600, 2600, Ex. J to Goldberg-Cahn Decl. As defendants admit, the only instance they know of in which direct oral suction during circumcision is performed is the Jewish ritual of metzitzah b'peh ("MBP"). See Tr. 33-34[1] ("We do acknowledge, as plaintiffs point out, that the only presently known conduct is in this

[1] References preceded by "Tr." refer to the transcript of the oral argument held on December 18, 2012.

particular religious ritual . . . . [W]e're only aware of direct oral suction in this religious context . . . .").

B. Metzitzah B'peh

Jewish ritual circumcision, known as a bris milah, or bris, is one of the core commandments of Jewish law. As explained by Rabbi Yona Metzger, the Chief Rabbi of Israel:

> The commandment of circumcision is among the most important in the Torah, and thirteen covenants were made (by G-d with the Jewish people) concerning it. It is the foundation of the bond between the Jew and his Creator, and ever since the Torah was given until today, the Jewish people have given their lives for it, throughout the generations, to fulfill it in accordance with all its details and fine points according to Torah law.

Yona Metzger, Call to the Public (July 23, 2012), Ex. D to Goldberg-Cahn Decl. [hereinafter Metzger, Call to the Public]. Rabbi Metzger elaborated that ritual circumcision involves three components: "the actual circumcision (removing the foreskin), peri'ah (revealing the glans), and metzitzah," or suction of blood away from the wound. Id.; see also Blum Aff. ¶ 3. A bris is traditionally performed on the eighth day of life, though it can be postponed in the interests of the baby's health. See Heber Aff. ¶ 4.

Plaintiffs introduced affidavits of several practicing ritual circumcisers, or mohels (also "mohelim"; singular: "mohel"), to establish the importance of MBP to the bris ritual and to provide background on how the ritual is performed. Rabbi

Levi Y. Heber, "an ordained Rabbi and a mohel certified by the American Board of Ritual Circumcision," has been performing brises for over eighteen years and "direct[s] and oversee[s] the operations of [plaintiff] the International Bris Association, a non-profit organization committed to promoting the sacred observance of the bris milah ritual, and providing education and information about this practice." Id. ¶¶ 1-2. Rabbi Heber testified:

> One of the critical components of the bris milah is the metzitzah stage. This involves orally drawing blood from the wound and surrounding areas. Metzitzah is an essential stage of the bris, required by Jewish law, and a mohel who does not follow the proper procedures in this regard is -- as a matter of Jewish law -- disqualified from service as a mohel.

Id. ¶ 5. Rabbi Heber elaborated that "[e]very mohel is trained with both medical knowledge and knowledge of Jewish law, or halakha, so that he can safely and properly perform the bris milah." Id. ¶ 4. Specifically with regard to metzitzah, Rabbi Heber stated that "the mohel is extensively trained to ensure that he performs the procedure both in accordance with Jewish law and without exposing either the child or the mohel to any physical harm." Id. ¶ 6. As examples of precautions taken by mohels, Rabbi Heber noted that a mohel will "absolutely not perform a bris if he is experiencing any cold sores," will "rinse [his] mouth[] with an antiseptic, such as alcohol or mouthwash, immediately before performing metzitzah," and will

"minimize the duration of the oral contact with the wound, so that it takes only approximately a second." Id. ¶ 7. In Rabbi Heber's experience, "these precautions are more than sufficient to assure the safety of metzitzah, which is performed tens of thousands of times every year without incident." Id. Finally, Rabbi Heber stated that mohels generally perform the bris ritual for purely religious reasons: "When a mohel performs the bris milah ceremony, his motivation is to faithfully comply with the requirements of Jewish law, and to respect and execute the sacred covenant between G-d and the Jewish People. Accordingly, most mohelim perform the bris without demanding any payment in exchange." Id. ¶ 8.

Plaintiffs also introduced affidavits from several other mohels, to similar effect. Rabbi Samuel Blum, one of the plaintiffs and a mohel who has "performed the bris milah hundreds of times" over the course of "approximately 47 years," testified that "Jewish law requires that metzitzah is to be performed using direct oral suction, i.e., the technique known as metzitzah b'peh." Blum Aff. ¶ 3. Rabbi Blum "therefore always conduct[s] MBP when [he] perform[s] the bris." Id. Rabbi Blum also testified that he regularly takes precautionary measures, including "rinsing [his] mouth with alcohol before performing MBP," and that he performs MBP "to faithfully comply with the requirements of Jewish law . . . without demanding any

payment in exchange." Id. ¶¶ 5-6. Rabbi Aharon Leiman, also a named plaintiff and "a mohel certified by the American Board of Ritual Circumcision" who has performed approximately 150 bris rituals over the course of approximately seven years, provided similar testimony, with the distinction that instead of rinsing with alcohol before performing MBP, he regularly rinses "with antiseptic mouthwash." Leiman Aff. ¶¶ 1, 5. Rabbi Shloime Eichenstein, a named plaintiff and "a mohel certified by the Ministry of Religion of the State of Israel" who has performed the bris ritual approximately 400 times over seven years, also provided similar testimony to that of Rabbis Blum and Leiman, noting that he "rins[es his] mouth with antiseptic mouthwash before performing MBP." Eichenstein Aff. ¶¶ 1, 5. Defendants, without questioning the sincerity of these mohels' religious belief that MBP is a required part of a bris, have noted that "other religious authorities within the Jewish faith approve different means" of suction than MBP that have not been shown to cause herpes infection, such as using a glass tube, sponge, or sterile gauze pad. DOHMH, Before the Bris: How to Protect Your Baby Against Infection (May 2012), Ex. V to Farley Decl., available at http://www.nyc.gov/html/doh/downloads/pdf/std/before-the-bris-brochure.pdf.

Although the mohels testified that they "do not believe that MBP, properly performed, exposes a child to the

transmission of any disease," Blum Aff. ¶ 5; see also Heber Aff. ¶ 7; Leiman Aff. ¶ 5; Eichenstein Aff. ¶ 5, DOHMH maintains that "none of the risk reduction measures suggested by Plaintiffs have been shown to reduce herpes transmission via direct oral suction." Farley Decl. ¶ 56; see also infra section C. [2] Accordingly, starting in 2005, the Department pursued several educational outreach measures regarding the risk of herpes transmission from MBP, see infra section D, and in September 2012 the Board of Health adopted section 181.21 to require informed consent prior to MBP, see infra sections E-F.

C. Herpes Simplex Virus

Herpes simplex virus ("HSV") is present in some form in most American adults. Farley Decl. ¶ 10. Two common manifestations of HSV are oral herpes and genital herpes, which are predominantly caused, respectively, by HSV type 1 ("HSV-1") and type 2 ("HSV-2"). Id. ¶ 8. HSV-1, the type at issue here,

[2] In support of their argument that "rinsing with antiseptic mouthwash has been scientifically proved to kill the herpes virus in the saliva," Aff. of Dr. Daniel S. Berman, M.D. ¶ 20, plaintiffs submitted a study published in the Journal of Clinical Periodontology which found that "the effects of rinsing with an essential oil containing mouthrinse (Cool Mint [Listerine Antiseptic]) resulted in effectively zero recoverable [herpes virus particles] at 30 [seconds] post rinse and this reduction in viral presence in saliva remained at a significant reduction for approximately 30 [minutes] for all experimental patients." Timothy F. Meiller et al., Efficacy of Listerine® Antiseptic in Reducing Viral Contamination of Saliva, 32 J. Clinical Periodontology 341, 345 (2005). However, the study concluded: "The clinical significance may be that reduction in infectious virus levels at the level demonstrated in these experiments significantly reduces, but may not eliminate, the risk of cross contamination. The necessary level for infectivity in saliva has not been determined and may be the subject of future studies." Id. (emphasis added).

is present in sixty percent of American adults and seventy-three percent of adults in New York City. Id. ¶ 10.

Although persons infected with HSV may exhibit symptoms such as "clusters of small, painful blisters that appear on the skin at the point where virus was originally introduced" and last for one to two weeks, HSV infection "does not usually cause symptoms" in adults. Id.; see also Kimberlin Aff. ¶ 4. By contrast, herpes in newborn infants "can be serious and life-threatening because newborn infants do not have fully developed immune systems." Farley Decl. ¶ 15. Approximately one-fifth of newborns infected with herpes die from their infection, and those who survive often suffer brain damage. Id.

A person may become infected with HSV after "com[ing] into contact with virus present in the saliva or genital secretions of an infected person," especially if the infected saliva or genital secretions reach a break in the person's skin. Id. ¶ 11. Among newborn infants infected with herpes, approximately eighty-five percent acquire the virus from their mother during birth as they come in contact with HSV-1 or HSV-2 present in the birth canal. Id. ¶ 13. Another five percent acquire the virus while in their mother's uterus, a process known as "congenital infection." Id. The remaining ten percent develop "postnatal infection," or infection after birth. Id. The total incidence of neonatal herpes is quite small: out of approximately 125,000

live births annually in New York City, there are only about 15 cases of neonatal herpes. Id. ¶ 16. The reason for this low incidence is that most infected mothers transfer antibodies against HSV to their babies through the placenta, and these "maternal antibod[ies]" generally protect the newborn against infection for several months after birth. Id. ¶¶ 14, 30. [3] However, if a mother does not become infected with herpes until the late stages of pregnancy, her body might not produce antibodies in time for them to be transferred to the baby prior to birth, and the baby will be at risk of herpes infection from the mother or other sources. Wald Aff. ¶ 19; see also Zenilman Aff. ¶ 16 ("Intrapartum transmission from mother-to-infant during delivery is most likely to occur when the maternal infection is acquired during the last trimester of pregnancy.").

Once a person is infected with HSV, blisters may appear at the location of transmission, though they need not, and a person may not know that he has been infected. Farley Decl. ¶¶ 8-10. The virus "travels up the sensory nerve supplying that section of skin where the initial contact occurred, and establishes permanent infection in that nerve, and (sometimes) in nerves that are adjacent at the level of the spinal cord." Id. ¶ 11; see also Kimberlin Aff. ¶ 4. The parties agree that HSV

[3] Plaintiffs argue that maternal antibodies do not necessarily prevent HSV infection, but they concede that, as a general matter, maternal antibodies provide effective resistance against infection. Tr. 7-8.

infection lasts for the life of the host and there is no known cure. Tr. 4-5.

Periodically, the virus "migrates from the nerve root, back down to the nerve endings, and emerges on the mucous membrane or skin supplied by that nerve." Kimberlin Aff. ¶ 4. The presence of HSV on a person's skin or mucous membrane may cause characteristic blisters, which may appear anywhere on the area of skin, known as a "dermatome," served by the infected nerve. Id.; Farley Decl. ¶ 11.[4] "Very frequently," however, HSV is present on a person's skin or mucous membrane without any symptoms -- a situation known as "asymptomatic viral shedding." Kimberlin Aff. ¶ 4; see also Tr. 4. As plaintiffs concede, asymptomatic viral shedding is intermittent and unpredictable, and the site of such shedding is infectious. Tr. 4. In other words, a person who has no visible symptoms of HSV, and who may not even know he is infected, may nonetheless have HSV present on his skin or mucous membrane and thus transmit HSV to persons with whom he comes in contact.

D. Prior Measures Taken to Address the Transmission of HSV-1

Prior to the Board of Health's adoption of section 181.21, DOHMH and New York State pursued several educational measures

[4] If HSV infection disseminates in the blood, blisters may also appear on other locations of the body. Farley Decl. ¶ 12.

regarding the risk of HSV-1 transmission from MBP. Commissioner Farley reports:

> Beginning in 2005, DOHMH participated in many meetings with leaders of the Jewish community to discuss the issue of HSV-1 infection associated with direct oral suction during circumcision. Many of the meetings were led by the then-DOHMH Commissioner Dr. Frieden, and included leaders of religious organizations, such as David Zweibel of Agudath Israel, leaders of the Central Rabbinical Congress, Rabbi David Niederman, then-New York City Councilmember Simcha Felder, Rabbi Yisroel Belsky, Dr. Kenneth Glassberg, Dr. Alan Wertzberger, among others.

Farley Decl. ¶ 70. Additionally, "on August 11, 2005, Mayor Michael Bloomberg and Commissioner Frieden met with a group of prominent rabbis and religious leaders at City Hall to discuss the issues of DOHMH's investigation into cases of neonatal HSV-1 infection connected to direct oral suction, and DOHMH's recommendation to cease direct oral suction." Id. ¶ 72.

On December 13, 2005, DOHMH distributed to the general New York City population, and posted on the DOHMH website, "An Open Letter to the Jewish Community from the New York City Health Commissioner" (the "Open Letter"). Letter from Thomas R. Frieden, Commissioner, DOHMH (Dec. 13, 2005), Ex. R to Farley Decl. [hereinafter Open Letter (2005)]; see also Farley Decl. ¶¶ 77, 80. The Open Letter stated that "in the Department's view there is no reasonable doubt that the practice of metzitzah b'peh ('suction by mouth') has infected several infants in New York City with the herpes virus, including one child who died

and another who has evidence of brain damage." Open Letter (2005), at 1. The letter discussed several cases of neonatal HSV-1 linked to MBP in New York City and cited three peer-reviewed studies that supported an association between MBP and HSV-1. Id. at 1-2 (citing Benjamin Gesundheit et al., Neonatal Genital Herpes Simplex Virus Type 1 Infection After Jewish Ritual Circumcision: Modern Medicine and Religious Tradition, 114 Pediatrics e259 (2004), Ex. J to Farley Decl. (reporting eight Israeli and Canadian cases of neonatal HSV-1 after MBP and finding that "the association between genital HSV-1 infection and the performance of the ancient procedure of oral metzitzah during the circumcision is strongly suggested" and that "it was most likely that the infection was transmitted directly from [the mohel's] oral or salivary contact," id. at e260); Rotem Distel et al., Primary Genital Herpes Simplex Infection Associated with Jewish Ritual Circumcision, 5 Israel Med. Ass'n J. 893 (2003), Ex. J to Farley Decl. (reporting one Israeli case of neonatal HSV-1 after MBP and stating that "the presence of HSV type 1 infection of the penis in an 18 day old infant raised suspicions that it was related to the circumcision performed a few days earlier[; t]his assumption was supported by several factors," id. at 894); Lorry G. Rubin & Philip Lanzkowsky, Cutaneous Neonatal Herpes Simplex Infection Associated with Ritual Circumcision, 19 Pediatric Infectious Disease J. 266

(2000), Ex. J to Farley Decl. (reporting two New York cases of neonatal HSV-1 after MBP and concluding that "[t]here are several lines of circumstantial evidence suggesting that the mohel who performed the circumcision was the source of the virus," id. at 267)). Based on this evidence, the Open Letter "recommend[ed] that infants being circumcised not undergo metzitzah b'peh," advised parents "to ask the mohel several days in advance of the bris whether he intends to perform metzitzah b'peh," and referenced a DOHMH webpage with information about the issue. Open Letter (2005), at 1-2. The Open Letter concluded by noting that although some medical professionals had encouraged DOHMH to ban MBP, the Department preferred "for the religious community to address these issues itself as long as the public's health is protected," and that "educating the community through public health information and warnings is a more realistic approach." Id. at 3.

Along with the Open Letter, DOHH distributed a fact sheet entitled "Before the Bris: How to Protect Your Infant Against Herpes Virus Infection Caused by Metzitzah B'peh" ("Before the Bris (2005)"). Ex. S to Farley Decl. [hereinafter Before the Bris (2005)]; see also Farley Decl. ¶ 80. This fact sheet, which was publicized and available through "311" and on the DOHMH website, presented information on the issue and warned that "[b]ecause there is no proven way to reduce the risk of

herpes infection posed by metzitzah b'peh, the Health Department recommends that infants being circumcised not undergo metzitzah b'peh." Before the Bris (2005); see also Farley Decl. ¶ 80. At the same time, DOHMH distributed a health alert both online and via the DOHMH Health Alert Network, which has approximately 22,300 subscribers in the New York City health community. DOHMH, 2005 Health Alert # 46: Neonatal Herpes Infection with Herpes Simplex Virus Type 1 Following Circumcision with Oral Suctioning (Metzitzah B'peh) (Dec. 13, 2005), Ex. T to Farley Decl. [hereinafter Health Alert (2005)]; see also Farley Decl. ¶ 81. The health alert informed physicians about the issue, advised them regarding how to handle possible cases of neonatal HSV, and reiterated that "because there is no proven way to reduce the risk of herpes infection posed by metzitzah b'peh, the Health Department advises against this practice." Health Alert (2005), at 4.

In parallel to DOHMH's efforts to combat the transmission of HSV through MBP, the New York State Department of Health (the "NYS Department of Health") also began to address the issue. Farley Decl. ¶ 73. Following meetings with religious leaders and DOHMH officials, the NYS Department of Health produced the Circumcision Protocol Regarding the Prevention of Neonatal Herpes Transmission (the "Protocol"), signed in June 2006 by Antonia C. Novello, the New York State Commissioner of Health,

several other NYS Department of Health officials, and numerous leaders in the Jewish community, including 28 rabbis. See Circumcision Protocol Regarding the Prevention of Neonatal Herpes Transmission, Ex. Q to Farley Decl. [hereinafter NYS Protocol (2006)]; see also Farley Decl. ¶¶ 73-76. The Protocol began by establishing several facts, including that "Herpes Simplex Virus (HSV) is known to cause rare, but very severe infections in newborns" and that "[b]ecause HSV-1 is known to be shed in saliva even while the person has no lesions or experiences no other signs or symptoms of active infection, there is a theory in some medical literature that, although extremely rare, the practice of metzizah b'peh could be a route of transmission for HSV-1." NYS Protocol (2006), at 1. Accordingly, the Protocol provided that "[p]arents . . . should be fully informed by the Rabbis regarding this" and required mohels or other persons performing MBP to take certain precautions, including using a mouthwash prior to performing MBP. Id. at 1-2.

The Protocol also established a testing regime if an infant on whom MBP was performed developed HSV within a period of time compatible with the HSV incubation period. During the NYS Department of Health investigation, which could last up to 45 days, the mohel would need to cease performing MBP. Id. at 3. The mohel would undergo serological testing (i.e. blood testing

for HSV antibodies) to determine if he had the same type of HSV as the infant did. Id. If the mohel had the same HSV type, he, along with up to four primary caregivers of the infant, would perform daily mouth swabs for up to a month to attempt to recover the virus itself. Id.; see also Simins Aff. ¶ 10. If virus from the mohel was recovered and had DNA identical to that of the virus recovered from the infant, the mohel would be deemed the source and would be banned from performing MBP for life. NYS Protocol (2006), at 4. If virus from the mohel was recovered and had DNA different from that of the virus recovered from the infant, or if virus was recovered from a caregiver and that virus matched the virus recovered from the infant, the mohel would be deemed not the source and could continue performing MBP. Id. Finally, if the mohel could not be definitely ruled out through DNA testing after a month of daily swabbing, he would be permitted to continue performing MBP if he took one 500 mg valacyclovir tablet either daily, if he participated frequently in circumcision with MBP, or every day for three days prior to performing a circumcision, if he participated in circumcisions with MBP only occasionally. Id. at 5.[5] The Protocol noted that although antiviral prophylaxis using drugs such as valacyclovir "has been shown to decrease

[5] The mohel also had the option of refraining from performing MBP until virus was recovered from him or a matching virus was recovered from a caregiver. NYS Protocol (2006), at 5.

clinical attacks" of HSV-1, "[t]here is no information regarding the effects of antiviral prophylaxis on HSV-1 shedding or transmission." Id.; see also Stanberry Aff. ¶ 13 ("[I]ndividuals on antiviral drugs can still transmit infection to newborn infants or susceptible sexual partners.").

As Commissioner Farley explains, DOHMH refused to endorse the Protocol, for several reasons.[6] For one, DOHMH objected to the precautions that the Protocol instructed mohels to perform, as "the effectiveness of those precautions in preventing transmission of herpes virus during direct oral suction has not been established." Farley Decl. ¶ 75. Additionally, DOHMH objected to "the agreed-upon testing protocol to establish the scientific link between any case of HSV-1 and a particular circumciser." Id. ¶ 76. New York State has since disavowed the Protocol. Simins Aff. ¶ 14.

The NYS Department of Health took further action on the issue in 2010, when it published its own "Before the Bris" brochure ("Before the Bris (2010)"). Farley Decl. ¶ 82. This brochure, which was distributed to all hospitals in New York State and posted on the NYS Department of Health and DOHMH websites, informed parents about the risk of herpes transmission

[6] The Protocol was endorsed by the 57 New York counties outside of New York City. Simins Aff. ¶ 14.

through MBP. Id.[7] Following meetings with rabbis, however, the NYS Department of Health removed Before the Bris (2010) from its website, though the brochure remained on the DOHMH website. Id. ¶ 83. At the invitation of the NYS Department of Health, a group of rabbis drafted their own brochure in 2011; although this brochure warned of a generic risk of infection, it did not specifically warn that herpes could be transmitted. Before the Bris: How to Protect Your Infant Against Infection, Ex. U to Farley Decl. [hereinafter Before the Bris (2011)]; see also Farley Decl. ¶ 84. The rabbis' brochure also advised parents that "[t]hose who follow the proper precautions and use mohelim that are experienced, cautious and careful should have no complications from the bris procedure." Before the Bris (2011).

DOHMH developed a new version of the Before the Bris brochure in early 2012 ("Before the Bris (2012)"). DOHMH, Before the Bris: How to Protect Your Baby Against Infection (May 2012), Ex. V to Farley Decl., available at http://www.nyc.gov/html/doh/downloads/pdf/std/before-the-bris-brochure.pdf [hereinafter Before the Bris (2012)]; see also Farley Decl. ¶ 85. Like the other educational materials distributed by DOHMH, this brochure informs parents about the issue and recommends against MBP. Before the Bris (2012). The Before the

[7] In 2010, the NYS Department of Health also distributed to mohels throughout New York State a document, entitled "Bris Milah Made Safer," which addressed the risk of herpes transmission from MBP. Farley Decl. ¶ 82 n.8.

Bris (2012) brochure is available online and remains in circulation. Farley Decl. ¶ 85. Additionally, Commissioner Farley announced on June 6, 2012, that several local hospitals, particularly hospitals that serve the Ultra-Orthodox Jewish community, had voluntarily agreed to distribute the Before the Bris (2012) brochure. DOHMH, Health Department Issues Statement Strongly Advising that Direct Oral-Genital Suction Not Be Performed During Jewish Ritual Circumcision (June 6, 2012), http://www.nyc.gov/html/doh/html/pr2012/pr017-12.shtml (last visited Jan. 10, 2013). Defendants clarified at oral argument that this agreement covers only "a small number of New York City hospitals." Tr. 29.

Although defendants have the authority to enter into voluntary agreements with hospitals, they would not have the authority to mandate that any privately operated hospital distribute the Before the Bris (2012) brochure. See N.Y. Pub. Health Law § 2812 (McKinney 2012) ("Notwithstanding the provisions of any general, special or local law, or any city charter or administrative code to the contrary, no county, town, village or city shall enact and enforce regulations and standards for hospitals, except for hospitals maintained and operated by the health services administration of the city of New York or the New York city health and hospitals corporation."); id. § 2800 ("[T]he [NYS] department of health

shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services . . . ."); see also NYC Bd. of Health Meeting Tr., Sept. 13, 2012, at 113, Ex. F to Goldberg-Cahn Decl. [hereinafter Bd. of Health Meeting Tr., Sept. 13, 2012] ("If the question is could we mandate that the hospitals give out this brochure, the answer is no. The Public Health Law specifically preempts us from regulating, localities from regulating hospitals. It's the state's job.") (statement of Thomas Merrill).

Finally, in June 2012, DOHMH posted online and disseminated an official statement regarding the risk of herpes transmission from MBP. DOHMH, New York City Statement on Jewish Ritual Circumcision with Direct Oral Suctioning – Metzitzah B'peh, Ex. W to Farley Decl., available at http://www.nyc.gov/html/doh/downloads/pdf/std/bris-statement.pdf [hereinafter NYC Statement on MBP (2012)]; see also Farley Decl. ¶ 87. The statement advised that "circumcision should always be done under sterile conditions" and that "[t]he Department also strongly advises that metzitzah b'peh with direct oral suctioning of the circumcision wound ('direct oral suctioning') never be performed." NYC Statement on MBP (2012). The statement reiterated the Department's commitment to "work with health care

providers, the community, and parents to prevent HSV-1 infection among newborn males undergoing ritual Jewish circumcision." Id.

In his declaration, Commissioner Farley reports that these educational outreach efforts have been a qualified success. On the one hand, DOHMH has reason to believe that its message regarding the risk of herpes transmission through MBP has reached a significant portion of the Orthodox Jewish community. The Department received more than 70 letters objecting to its involvement in regulating MBP between June and August 2005; the City's "311" service received more than 750 phone calls about the issue in 2005; and, the Before the Bris (2010) and Before the Bris (2012) brochures posted on the DOHMH website have received more than 11,000 hits since January 2011. Farley Decl. ¶ 90. Additionally, the Department has reason to believe that its message has reached the Jewish medical community, as suggested by several sessions at Jewish medical conferences devoted to the medical risks of MBP. Id. ¶ 92.

On the other hand, DOHMH believes that a serious health risk remains despite the educational outreach campaign. Although, as plaintiffs point out, the fact that MBP continues to be practiced could simply be a sign that parents support it, all things considered, Tr. 29, more troubling evidence lies in the fact that "DOHMH has continued to receive complaints from parents after their infant had a circumcision that included

direct oral suction without their prior knowledge or permission that such would occur." Farley Decl. ¶ 94. These complaints, which have come both from parents whose children contracted HSV-1 and from parents whose children did not, have continued through June 2012. See id.; Tr. 29, 31.[8]

With this extensive history of educational outreach to inform parents about the risks of MBP, the Department took a further step in June 2012 by proposing the present regulation.

E. Legislative History of Section 181.21

On June 12, 2012, DOHMH officials proposed to the Board of Health an amendment to the New York City Health Code requiring persons performing circumcisions involving direct oral suction to first obtain a parent's informed consent. NYC Bd. of Health Meeting Tr., June 12, 2012, at 78-83, Ex. A to Goldberg-Cahn Decl. [hereinafter Bd. of Health Meeting Tr., June 12, 2012]. In support of the proposed regulation, the DOHMH officials, Drs. Varma and Schillinger, presented the results of a study conducted by DOHMH and published in the June 8, 2012, issue of

[8] With regard to the complaint from June 2012, plaintiffs note that the record does not contain information regarding the circumstances or date of the infant's circumcision. Tr. 32. However, the fact remains that at least some weight should be attributed to the complaint in light of the not-insubstantial likelihood that a circumcision reported in June 2012 was performed in June 2012, and specifically after the Department's agreement to distribute Before the Bris (2012) brochures in certain hospitals, which was announced on June 6, 2012. See DOHMH, Health Department Issues Statement Strongly Advising That Direct Oral-Genital Suction Not Be Performed During Jewish Ritual Circumcision (June 6, 2012), http://www.nyc.gov/html/doh/html/pr2012/pr017-12.shtml (last visited Jan. 10, 2013). By June 2012, moreover, DOHMH had already taken several steps to educate the Jewish community about the risk of herpes transmission from MBP.

the Centers for Disease Control and Prevention ("CDC")'s Morbidity and Mortality Weekly Report ("MMWR") (the "MMWR Study"). Id. at 80-82; see also Susan Blank et al., Neonatal Herpes Simplex Virus Infection Following Jewish Ritual Circumcisions that Included Direct Orogenital Suction – New York City, 2000-2011, 61 Morbidity and Mortality Weekly Rep. 405 (2012), Ex. K to Farley Decl. [hereinafter MMWR Study (2012)]. As Dr. Varma explained, the Department had found, since 2000, eleven laboratory-confirmed cases of neonatal herpes in infants who had undergone a circumcision that definitely or likely involved direct oral suction.[9] Bd. of Health Meeting Tr., June 12, 2012, at 80. Of those eleven cases, two infants died and two suffered brain damage. Id. Dr. Varma reported that DOHMH calculated the rate of herpes infection following direct oral suction to be one in 4,098, which was three to four times greater than the risk of herpes infection for males in New York City who did not have direct oral suction performed. Id. at 80-81; see also MMWR Study (2012), at 406-07. As evidence of a causal link between direct oral suction and neonatal herpes infection, Dr. Varma cited the location of the lesions, the

[9] DOHMH was unable to confirm that direct oral suction occurred in five of the eleven cases because, although the infants were members of communities in which direct oral suction could be expected to occur, "family members were unwilling to describe for [DOHMH] in detail what procedure actually occurred." Bd. of Health Meeting Tr., June 12, 2012, at 80; see also MMWR Study (2012), at 406.

timing of symptom onset, a cluster of three cases related to one mohel, the fact that the cases mostly involved HSV-1,[10] commonly found in the mouth, and a statistically significant correlation between direct oral suction and herpes infection. Bd. of Health Meeting Tr., June 12, 2012, at 81-82. Dr. Varma also noted that the Department had received several complaints from parents that they were not aware ahead of time that direct oral suction would be performed on their child. Id. at 82. Following DOHMH's presentation and a period for questions and comments by members of the Board of Health, the Board approved the proposed regulation for publication. Id. at 101-02. One week later, DOHMH published a Notice of Public Hearing in The City Record setting forth the proposed regulation and the time and place of the public hearing. Notice of Public Hearing, The City Record, June 19, 2012, at 1581, Ex. B to Goldberg-Cahn Decl. [hereinafter Notice of Public Hearing, June 19, 2012].

On July 23, 2012, as noticed, DOHMH held a hearing on the proposed regulation. DOHMH Public Hearing Tr., July 23, 2012, Ex. C to Goldberg-Cahn Decl. [hereinafter DOHMH Public Hearing Tr., July 23, 2012]. Only three persons appeared at the hearing to speak, each of whom was a rabbi associated with the American Board of Ritual Circumcision or the International Bris

[10] Nine of the eleven cases were confirmed to involve HSV-1; the remaining two "were untyped because specimens were not tested appropriately." Bd. of Health Meeting Tr., June 12, 2012, at 82; see also MMWR Study (2012), at 406.

Association. Id. at 5, 7, 11. The rabbis opposed the proposed rule, informing the Department that their organizations had utmost concern for infants' health and already had in place strict regulations concerning how ritual circumcisions should be performed. Id. at 5-15. In addition to this oral testimony, DOHMH received twenty-one written comments from eighteen diverse sources, eleven of which supported the proposed rule and seven of which opposed it. Goldberg-Cahn Decl. ¶¶ 12-16; see also Ex. D to Goldberg-Cahn Decl.

On September 12, 2012, two additional letters were sent to Mayor Bloomberg, with copies to Commissioner Farley, in support of the proposed regulation. The first letter was from Dr. Janet A. Englund, MD, President of the Pediatric Infectious Diseases Society ("PIDS"). Letter from Janet A. Englund, MD, to Mayor Michael R. Bloomberg (Sept. 12, 2012), Ex. E to Goldberg-Cahn Aff. PIDS "is the world's largest organization of professionals dedicated to the treatment, control and eradication of infectious diseases affecting children, and has many active members who are involved in public policy and provide care for children in New York City and around the country." Id. Dr. Englund advised that "any oral contact to a break in the infant's skin, particularly at the point and time of circumcision, puts the baby at highest risk for potentially acquiring a life-threatening and frequently lethal herpes

infection." Id. Because of the serious consequences of neonatal herpes, Dr. Englund concluded that "the risks associated with MBP should be clearly communicated to parents or legal guardians in advance of the procedure." Id. Therefore, PIDS "support[ed] the informed consent requirement currently under consideration and urge[d] approval by the Board of Health." Id.

The second letter was from Dr. Thomas G. Slama, MD, President of the Infectious Diseases Society of America ("IDSA"). Letter from Thomas G. Slama, MD, to Mayor Michael R. Bloomberg (Sept. 12, 2012), Ex. E to Goldberg-Cahn Decl. IDSA "represents nearly 10,000 physicians and scientists devoted to patient care, education, research, and public health in infectious diseases." Id. Dr. Slama determined that "[t]he epidemiological investigations conducted by [DOHMH] present strong evidence that herpes simplex virus type 1 (HSV-1) can be transmitted to a newborn when circumcision involves direct orogenital suction of the penile incision." Id. Because neonates have underdeveloped immune systems and are thus at risk of "death or permanent disability" from HSV infection, Dr. Slama concluded that "the risks associated with MBP as well as the importance of practicing circumcisions and related procedures in a sterile environment should be clearly communicated to parents or legal guardians in advance of the procedure." Id.

Accordingly, IDSA "support[ed] the informed consent requirement currently under consideration and urge[d] the Board of Health to approve it." Id.

On September 13, 2012, the Board of Health held a public meeting to consider the final draft of the proposed regulation. Bd. of Health Meeting Tr., Sept. 13, 2012. At the meeting, DOHMH officials summarized the comments they had received and their responses to those comments. Id. at 87-102. In response to a comment that there was actually no evidence showing an association between MBP and HSV, Dr. Varma cited not only the MMWR Study, but also the three additional studies published in peer-reviewed journals, discussed above, that found an association between MBP and HSV, and "a wide body of expert opinion and evidence" indicating such an association. Id. at 93; see also Gesundheit et al., supra; Distel et al., supra; Rubin & Lanzkowsky, supra; Tr. 19 ("[T]he Department of Health & Mental Hygiene was quite aware of those [three] studies before it even set out to do the surveillance data that's in the [MMWR Study] . . . ."). Dr. Varma elaborated:

> [L]eaders in the field of infectious diseases, in pediatrics, in public health, all agree that herpes virus can be transmitted during direct oral suction. There are institutions that have either published statements or written letters to the Mayor, in fact, including the Centers for Disease Control, the American Academy of Pediatrics, the Infectious Disease[s] Society of America and the Pediatric Infectious Disease[s] Society of America, all who come

> to the exact same conclusion that we have. And we would also make the point that even if there was some uncertainty, we think that there is sufficient evidence that parents need to be aware about the opinions of experts on this matter.

Bd. of Health Meeting Tr., Sept. 13, 2012, at 94-95.

With regard to the MMWR Study itself, Dr. Varma stated that the Department had considered several comments criticizing the study, but still "st[ood] firmly by the data, the interpretation and the conclusion." Id. at 91. In response to a comment that the Department had failed to investigate sources of HSV other than mohels, Dr. Varma reported that "the Department did, in fact, investigate many possible sources of infection" and had concluded that "the likely source of infection, the most highly likely source" was the mohels. Id. at 90. In response to a comment that the Department needed DNA evidence to show an association between MBP and HSV, Dr. Varma argued that DNA evidence was not necessary in light of multiple other lines of evidence, and moreover that the reason DNA evidence was not used is that obtaining specimens is difficult, given the intermittency and unpredictability of viral shedding, and the Department faced problems in "actually getting cooperation from various people involved in the investigation to actually provide us with specimens sufficient for testing." Id. at 92; see also id. at 93.

Other comments, Dr. Varma noted, had suggested that DOHMH ban direct oral suction outright. Id. at 97. Dr. Varma reported that the Department chose not to pursue this approach in light of the competing interests at stake; the Department was "really seeking the most narrow approach possible to fulfill its mandate and not impede religious practices." Id. The Department had also sought to make the regulation more accommodating of mohels' free speech interests by replacing a requirement that parents consent using "a form approved or provided by the Department," Notice of Public Hearing, June 19, 2012, at 1582, with a requirement that parents consent using "a form provided by the Department or a form which shall be labeled 'Consent to perform oral suction during circumcision,' and which at a minimum shall include" certain minimum elements, Notice of Adoption of an Amendment to Article 181 of the New York City Health Code, The City Record, Sept. 21, 2012, at 2600, Ex. J to Goldberg-Cahn Decl. [hereinafter Notice of Adoption, Sept. 21, 2012]. See Bd. of Health Meeting Tr., Sept. 13, 2012, at 101. With regard to the forms provided by the Department, Dr. Varma made clear that such forms "will certainly be available both by the internet and printed copies that we can make available to people that request it." Id. at 105.

Regarding enforcement, Dr. Varma indicated that it would be "impractical for [DOHMH] to be actually monitoring circumcisions

to make sure that consent is performed adequately." Id. at 108. Therefore, the Department expected enforcement to occur primarily in two situations: (1) where the Department receives a complaint from a parent that MBP was performed without the parent's prior knowledge, and (2) where the circumcised infant develops neonatal herpes. Id.

As to alternative ways to educate parents, Dr. Varma stated:

> We have gotten the permission of many hospitals in New York City, particularly the hospitals that largely serve this population, to distribute a brochure that we are publishing entitled, "Before the Bris." It is available both in English as well as in Yiddish to educate families about this exact issue, and it is meant to be delivered to parents, mothers and fathers of babies that are born in these hospitals and that have males [that] are likely to undergo circumcision. We hope that this is also one additional way that parents are educated and knowledgeable about this.

Id. at 111-12; see also Before the Bris (2012). As discussed above, however, this agreement covers only a small subset of New York City hospitals, Tr. 29, and DOHMH would not have authority to mandate that any privately operated hospital distribute the brochure. See N.Y. Pub. Health Law §§ 2800, 2812 (McKinney 2012); see also Bd. of Health Meeting Tr., Sept. 13, 2012, at 113.

At the conclusion of the meeting, Commissioner Farley, the Chair of the Board of Health, made the following remarks:

> This is an issue which is a very difficult issue, as I am sure all the Board Members know, that people in the [a]ffected community, many of them feel very, very strongly about this practice. This is a practice that has been taking place for hundreds, if not thousands of years, and [they believe] that government has no role in inserting itself into this at all. So the Department is trying to be very careful here in its role in protecting the health of infants while also being respectful of religious traditions, which we are certainly very supportive of the idea of religious traditions.
>
> I think the Board members know that we have received communications from people who are concerned about this and asked that there be greater dialogue with the Department and that this vote be delayed for greater dialogue. Let me just say that we welcome dialogue around this issue, we think that that is a good thing. We want to work with the community as much as possible.
>
> But I also think that delaying at this point would be essentially doing nothing and there is a risk that we may be getting more infections between now and the next meeting. So I think we can take action today, while still continuing the dialogue with this community. And if we feel in the future that a different approach is a better approach than this, based upon our discussion with the community, we can certainly bring that back to the Board.

Bd. of Health Meeting Tr., Sept. 13, 2012, at 114-15. The Board of Health then approved the new section 181.21 by unanimous vote. Id. at 115-16.

F. The Final Regulation and Associated Materials Published in The City Record

As stated above, the final regulation reads as follows:

> § 181.21 Consent for direct oral suction as part of a circumcision.
>
> (a) Direct oral suction means contact between the mouth of a person performing or assisting in the

> performance of a circumcision and an infant's circumcised penis.
>
> (b) Written consent required. A person may not perform a circumcision that involves direct oral suction on an infant under one year of age, without obtaining, prior to the circumcision, the written signed and dated consent of a parent or legal guardian of the infant being circumcised using a form provided by the Department or a form which shall be labeled "Consent to perform oral suction during circumcision," and which at a minimum shall include the infant's date of birth, the full printed name of the infant's parent(s), the name of the individual performing the circumcision and the following statement: "I understand that direct oral suction will be performed on my child and that the New York City Department of Health and Mental Hygiene advises parents that direct oral suction should not be performed because it exposes an infant to the risk of transmission of herpes simplex virus infection, which may result in brain damage or death."
>
> (c) Retention of consent forms. The person performing the circumcision must give the parent or legal guardian a copy of the signed consent form and retain the original for one year from the date of the circumcision, making it available for inspection if requested by the Department.

Notice of Adoption, Sept. 21, 2012, at 2600.

The regulation was published in the September 21, 2012, issue of The City Record. Id. Along with the enacted regulation, The City Record published the regulation's Statement of Basis and Purpose:

> Statement of Basis and Purpose
>
> The purpose of this amendment is to require written consent from a parent or legal guardian when direct oral suction will be performed during his or her son's circumcision. The written consent will require that the parent or guardian has been told that

the Department advises against direct oral suction because of certain risks associated with the practice, including infection with herpes simplex virus and its potentially serious consequences, such as brain damage and death. Knowing the risks posed by direct oral suction, a parent or legal guardian can then make an informed choice about whether it should be performed as part of the circumcision.

The amendment requires persons performing circumcisions which include direct oral suction to retain copies of signed consent forms for at least one year and to make them available to the Department upon request.

Background

Male circumcision, which involves cutting off skin and leaving an open wound on the penis, carries a risk for infection. It should be performed under sterile conditions to protect the open wound from infection. There is a practice involving direct contact between the mouth of a person performing or assisting in performing a circumcision and the infant's circumcised penis ('direct oral suction'). When direct oral suction is performed as part of circumcision, there is a risk that the person performing direct oral suction will transmit herpes simplex virus to the infant being circumcised.

Between 2004 and 2011, the Department learned of 11 cases of laboratory-confirmed herpes simplex virus infections in male infants following circumcisions that were likely to have been associated with direct oral suction. Two of these infants died, and at least two others suffered brain damage. The parents of some of these infants have said that they did not know before their child's circumcision that direct oral suction would be performed. In addition, since 2004, the Department has received multiple complaints from parents whose children may not have been infected with herpes simplex virus or other infectious diseases but who were also not aware that direct oral suction was going to be performed as part of their sons' circumcisions.

The Amendment

The new Health Code provision, §181.21 -- Consent for direct oral suction as a part of circumcision -- requires that if direct oral suction is to be performed as part of a circumcision, the person performing the circumcision must obtain prior written consent from a parent or legal guardian. The written consent would document that a parent has been given notice that direct oral suction is to be performed and that the parent has been informed that the Department advises against direct oral suction because the practice carries a risk of transmission to the infant of herpes simplex virus infection. A copy of the signed consent form must be given to the parent or legal guardian signing the consent. The person performing the circumcision will have to maintain the original for at least one year after the circumcision is performed, and make it available for inspection at the request of the Department.

In response to comments received, the resolution has been amended to allow use of a consent form other than one approved and provided by the Department if the form used contains certain elements deemed necessary for a parent or legal guardian to document that she or he has given consent. The language of the consent now includes a reference to the Department's concerns about the risks of direct oral suction, and indicates that the consent must be obtained by the person performing the circumcision whenever direct oral suction is performed regardless of whether this person performs direct oral suction himself or it is done by another person assisting him.

Notice of Adoption, Sept. 21, 2012, at 2600. The published regulation was also followed by a "note":

[Section] 181.21 was added to Article 181 by resolution adopted September 13, 2012 to require that persons who perform circumcisions on infants under one year of age that include the application of direct oral suction obtain the written consent of a parent prior to performance of the circumcision and warn the

> parent of the Department's concerns about the risks of infection posed by direct oral suction.

Id. An additional "note" read:

> Article 181 was amended by resolution adopted September 13, 2012 adding a new §181.21 requiring written parental consent for circumcisions performed on an infant under one year of age that includes the application of direct oral suction to the infant's penis in view of the Department's concerns about the risks of transmission of infection to such infants through the practice of direct oral suction.

Id. The regulation was scheduled to enter into force on October 21, 2012, thirty days after its publication in The City Record. Goldberg-Cahn Decl. ¶ 28; see also NYC Charter § 1043(e) (2009). However, on October 11, 2012, plaintiffs filed suit in this Court seeking declaratory and injunctive relief barring enforcement of section 181.21. On October 17, 2012, the parties stipulated:

> No Defendant will act in any manner to enforce Section 181.21 of the New York City Health Code from its effective date on October 21, 2012 until the date of oral argument on Plaintiffs' motion for a preliminary injunction . . . nor will any Defendant undertake to enforce Section 181.21 in any manner at any time thereafter in connection with circumcisions performed between October 21, 2012 and the date and time of oral argument on Plaintiffs' motion for a preliminary injunction.

Stipulation, Oct. 17, 2012, ¶ 1. The Court so-ordered the Stipulation on October 22, 2012. At the oral argument on December 18, 2012, we extended the stay of enforcement until

such time as we ruled on plaintiffs' motion for a preliminary injunction.

G. The Parties' Positions on the Science of HSV-1 Transmission

In support of their position that MBP places infants at a serious risk of HSV-1 infection, defendants offer the testimony of five experts in the field of infectious diseases, in addition to the testimony of Commissioner Farley. First, Dr. Richard J. Whitley, MD, president of the Infectious Diseases Society of America and the Distinguished Professor of Pediatrics, Microbiology, Medicine, and Neurosurgery and Loeb Eminent Scholar Chair in Pediatrics at the University of Alabama at Birmingham. Whitley Aff. ¶ 1. Second, Dr. David Kimberlin, MD, president-elect of the Pediatric Infectious Diseases Society as well as Professor of Pediatrics and holder of the Sergio Stagno Endowed Chair in Pediatric Infectious Diseases at the University of Alabama at Birmingham. Kimberlin Aff. ¶ 1. Third, Dr. Lawrence R. Stanberry, MD, Ph.D., Chair of the Department of Pediatrics at the College of Physicians and Surgeons of Columbia University and Pediatrician-in-Chief of the New York-Presbyterian Morgan Stanley Children's Hospital. Stanberry Aff. ¶ 1. Dr. Stanberry has authored over 100 articles, reviews, and chapters that pertain to HSV infection and has edited several textbooks including Genital and Neonatal Herpes and Sexually

Transmitted Diseases: Vaccines, Prevention, and Control. Id. ¶¶ 4-5. Fourth, Dr. Jonathan Zenilman, MD, Professor of Medicine at the Johns Hopkins University School of Medicine and Chief of the Infectious Diseases Division at the Johns Hopkins Bayview Medical Center in Baltimore, Maryland. Zenilman Aff. ¶ 1. Dr. Zenilman served in the CDC's Division of Sexually Transmitted Diseases for four years prior to joining the Johns Hopkins faculty in 1989, and was president of the American Sexually Transmitted Diseases Association from 2004 to 2008. Id. ¶¶ 1, 3-4. Fifth, Dr. Anna Wald, MD, MPH, Professor of Medicine, Epidemiology, and Laboratory Medicine at the University of Washington. Wald Aff. ¶ 2. Dr. Wald has authored more than 200 peer-reviewed published manuscripts about HSV infection, and since 1997 has helped draft guidelines on management of HSV infection for the CDC's Sexually Transmissible Disease Treatment Guidelines. Wald Aff. ¶ 3.

Each of these experts provided independent testimony that direct oral suction puts infants at risk of HSV-1 infection. See Whitley Aff. ¶ 5 ("[T]here is a definite scientific link between direct oral suction as part of circumcision and neonatal herpes type 1 infection."); Kimberlin Aff. ¶ 8 ("[N]eonates exposed to circumcision that includes direct oral suction are more likely to become infected with herpes simplex [virus] type 1 or untyped herpes simplex virus infection[] than neonates that

do not have this exposure."); Stanberry Aff. ¶ 14 ("Regardless of any perceived epidemiological flaws in the MMWR [Study], we know for certain that mouth to penis contact can result in transmission of HSV-1 -- hence, we know that the risk of neonatal herpes resulting from direct oral suction is real."); Zenilman Aff. ¶ 20 ("It is my professional opinion that suctioning of the fresh circumcision wound puts uninfected infants at risk of acquiring HSV-1 and developing serious illness."); Wald Aff. ¶ 20 ("[T]he evidence linking direct oral suction with neonatal HSV infection is strong, consistent, and more than biologically plausible.").

Additionally, defendants are supported by an amicus submission on behalf of the American Academy of Pediatrics, the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the American Sexually Transmitted Diseases Association. Letter from Akiva Shapiro to the Court (Nov. 16, 2012) [hereinafter Amicus Submission]. These organizations "are the nation's foremost professional organizations of pediatrics, infectious diseases, pediatric infectious diseases, and sexually transmitted diseases physicians." Id. at 1. Amici advise that "it is incontrovertible that infectious diseases can be, and have been, transmitted through direct orogenital suction of the penile incision during circumcision ('direct oral suction'), and that direct oral suction increases the risk that a neonate will

acquire herpes simplex virus ('HSV') and other communicable diseases." Id. In support of this claim, amici cite not only the MMWR Study, but also two other studies relied on by DOHMH -- the 2004 study published in Pediatrics and the 2000 study published in the Pediatric Infectious Disease Journal -- and "[t]wo hundred years of historical data [that] supports the straightforward proposition that direct oral suction increases the risk of transmission of HSV and other infectious diseases." Id. at 3; see also id. at 4 (noting multiple nineteenth-century studies linking MBP to neonatal syphilis and observing that "the historical record contains numerous other instances of infectious disease transmission through direct oral suction, including of tuberculosis to the penis and syphilis"). Amici conclude that parental consent should be required prior to MBP "[g]iven the overwhelming scientific evidence demonstrating the increased likelihood that newborns subject to direct oral suction will acquire HSV and that, because neonatal immune systems are underdeveloped, HSV infection in newborns is more likely to result in death or permanent disability." Id. at 4.

Facing what appears to be a strong scientific consensus that direct oral suction puts infants at a serious risk of HSV-1 infection, plaintiffs concede that it is "biologically possible" for HSV-1 to be transmitted through oral contact with an open wound on the genitals. Tr. 4. What plaintiffs dispute is

"whether that has actually ever happened in the context of this particular religious ritual, metzitzah b'peh." Tr. 3. In other words, although plaintiffs acknowledge that it is "theoretically possible" for MBP to cause HSV-1 infection, Tr. 3, they maintain that it has never been "show[n] definitely that HSV has been transmitted by MBP." Tr. 24. Consistent with this strategy, plaintiffs do not attempt to discredit the prominent academics and national medical organizations that argue that MBP places infants at a serious risk of HSV-1 infection, but rather limit their expert testimony to attacking the eleven cases of neonatal herpes linked by the MMWR Study to MBP. Plaintiffs maintain that undermining the MMWR Study is sufficient to defeat the regulation because under strict scrutiny analysis, the government must demonstrate that it is addressing an "actual problem," not merely a risk that might or might not materialize. Pls.' Mem. of Law in Supp. of Pls.' Mot. for a Prelim. Inj. 26 [hereinafter Pls.' Mot.] (quoting Brown v. Entm't Merchs. Ass'n, 131 S. Ct. 2729, 2738 (2011)) (internal quotation mark omitted).

However, contrary to plaintiffs' position, strict scrutiny does not apply here. As demonstrated below in sections III.B and III.C, the regulation neither compels speech nor impermissibly burdens plaintiffs' free exercise of religion. Accordingly, defendants need not show an "actual problem" in need of solving, and consequently the showing legally required

to demonstrate an "actual problem" is immaterial, as is whether defendants have made such a showing. What is clear is that plaintiffs do not defeat section 181.21 simply by attacking the particular cases of neonatal herpes linked by DOHMH to MBP. Likewise, it would not be dispositive if, as plaintiffs allege, defendants did not demonstrate a statistically significant link between MBP and HSV infection. Rather, plaintiffs would need to establish that the totality of the evidence accumulated by defendants is insufficient to demonstrate that the regulation is rationally related to a legitimate governmental interest.

Plaintiffs do not seriously attempt to meet this burden, but instead focus on discrediting the MMWR Study. Because, as discussed below, the evidence submitted by defendants and amici other than the MMWR Study is sufficient to deny plaintiffs' motion for a preliminary injunction, we reach our decision without resolving the disputed questions of fact relating to the MMWR Study.[11] That said, for the sake of completeness, we summarize here plaintiffs' arguments on the MMWR Study and defendants' responses thereto.

Plaintiffs' primary medical expert is Dr. Daniel S. Berman, MD, a medical doctor specializing in infectious diseases. Aff. of Dr. Daniel S. Berman, M.D. ¶ 1 [hereinafter Berman Aff. I].

[11] For similar reasons, as discussed below, we need not hold an evidentiary hearing prior to ruling on plaintiffs' motion for a preliminary injunction. See Charette v. Town of Oyster Bay, 159 F.3d 749, 755 (2d Cir. 1998).

Dr. Berman has served as the Chief of Infectious Diseases at the New York Westchester Square Hospital Medical Center since 1989 and is on the attending staff at the Montefiore Medical Center as an Infectious Diseases specialist. Id. Dr. Berman's criticism of the MMWR Study may be divided into three categories. First, Dr. Berman argues that there is insufficient evidence linking MBP to HSV-1 infection beyond mere plausibility. Id. ¶¶ 3, 13; Supplemental Aff. of Dr. Daniel S. Berman, M.D. ¶¶ 4-25 [hereinafter Berman Aff. II]. With regard to the timing of HSV-1 infection, for instance, he argues that the timing of four of the eleven cases is inconsistent with transmission through MBP. Berman Aff. II ¶¶ 9-17. Second, Dr. Berman argues that the MMWR Study does not sufficiently rule out alternative modes of HSV-1 transmission. According to Dr. Berman, the study does not sufficiently account for the possibility of transmission from parents or other household sources, Berman Aff. I ¶¶ 13, 16, 18; Berman Aff. II ¶¶ 26-38, and, because it does not incorporate DNA testing, cannot definitely prove that any of the cases of neonatal herpes infection were caused by a particular mohel rather than another source, Berman Aff. I ¶ 19; Berman Aff. II ¶ 2. Finally, Dr. Berman argues that the MMWR Study's statistical analysis is flawed because it significantly underestimates the total number of infants who have MBP performed each year -- the denominator

in the study's calculation of the rate of HSV-1 infection following MBP. Berman Aff. I ¶ 15.

Plaintiffs also offer the testimony of Dr. Awi Federgruen, D.Sc., the Charles E. Exley Professor of Management and former Chair of the Decision, Risk and Operations Division of the Graduate School of Business at Columbia University. Aff. of Dr. Awi Federgruen, D. SC. ¶ 1 [hereinafter Federgruen Aff. I]. Dr. Federgruen is "an expert in various areas of quantitative methodology." Id. Expanding on a point made by Dr. Berman, Dr. Federgruen argues that using a corrected figure for the total number of children on whom MBP is performed would eliminate the MMWR Study's finding of a statistically significant link between MBP and HSV-1 infection. Id. ¶¶ 3, 7-12; Supplemental Aff. of Dr. Awi Federgruen, D.SC. ¶¶ 4-15 [hereinafter Federgruen Aff. II]; see also Schick Aff.; Zucker Decl. ¶ 4-6. Dr. Federgruen also objected to the statistical methodology employed by DOHMH in calculating the confidence interval presented in the MMWR Study, Federgruen Aff. I ¶ 6; Federgruen Aff. II ¶¶ 16-20, and argued that, because the number of cases reported in the MMWR Study was small, a more robust analysis would have included data from Israel, Federgruen Aff. I ¶ 4.

Finally, plaintiffs offered the testimony of Dr. Brenda Breuer, Ph.D., MPH, Director of Epidemiologic Research at the Department of Pain Medicine and Palliative Care at the Beth

Israel Medical Center in New York and an Associate Professor of Clinical Neurology at the Albert Einstein College of Medicine in New York. Breuer Aff. ¶ 1. Dr. Breuer seconded Dr. Federgruen's conclusion that the statistical methodology employed by the MMWR Study was inappropriate, id. ¶ 8, and added that the MMWR Study insufficiently accounted for the possibility of transmission through hospital sources, id. ¶ 10. Finally, Dr. Breuer faulted the MMWR Study for failing to set a timeframe or sample size parameters in advance. Id. ¶¶ 6-7; see also Zucker Decl. ¶ 7.

In response, Drs. Whitley, Kimberlin, and Zenilman explicitly testified that DOHMH's data, along with other published data on the subject, constituted compelling evidence of a link between MBP and HSV-1 infection. See Whitley Aff. ¶¶ 5, 18-19; Kimberlin Aff. ¶¶ 3, 8; Zenilman Aff. ¶ 24. With regard to the criticism that there was no independent evidence linking MBP to HSV-1 infection, plaintiffs' experts noted numerous indications of such a link, including the location of symptoms, the timing of symptom onset, and clustering of several cases around certain mohels and in a certain geographic area. Farley Decl. ¶¶ 42-43, 58-60; Kimberlin Aff. ¶ 6; Wald Aff. ¶¶ 9-15; Zenilman Aff. ¶¶ 24-27. With regard to criticism that DOHMH had not sufficiently accounted for transmission through household or hospital sources, defendants' experts explained

that the study had accounted for alternative routes of transmission and that, whereas several lines of evidence supported transmission through MBP, transmission from household, hospital, or other sources was unlikely.[12] Farley Decl. ¶¶ 44-45, 61; Stanberry Aff. ¶ 16; Zenilman Aff. ¶¶ 33.

With regard to the criticism that the MMWR Study underestimated the total population of infants on whom MBP is performed, defendants' experts argued that even if the demographic data submitted by plaintiffs' experts were correct, with the result that a statistically significant association between MBP and HSV-1 infection did not exist, other evidence would still be sufficient to demonstrate a causal relationship. Dr. Wald explained that "[t]here are several issues to consider when evaluating whether there is a causal relationship between 2 events. These are formally known in epidemiology as Bradford Hill criteria." Wald Aff. ¶ 9. The three most important such criteria, not all of which need be satisfied in order for causality to be established, are "(1) biologic plausibility; (2) temporality; and (3) strength of association." Id. An additional affidavit by Dr. Andrew Gelman, Ph.D., Professor of Statistics and Political Science and Director of the Applied

[12] Moreover, even putting aside defendants' experts' testimony that alternative routes of transmission were unlikely, plaintiffs' experts never showed that their suggested alternative routes of transmission were more likely than transmission through MBP.

Statistics Center at Columbia University, Gelman Decl. ¶ 1, similarly established that "statistical significance is not a necessary condition that must be met to establish an important and meaningful relationship between an exposure and an outcome, particularly when there are other lines of evidence for doing so," id. ¶ 19. Statistical significance, in other words, "is just one piece of the puzzle." Id. ¶ 26. As Dr. Gelman concluded, the available evidence of a link between MBP and HSV-1 was sufficient to indicate a causal relationship even absent a finding of statistical significance. Gelman Decl. ¶ 26.

Dr. Gelman also responded to several of plaintiffs' experts' statistical criticisms. Dr. Gelman explained that a surveillance study with parameters not set in advance was statistically acceptable absent indications of selection bias, of which there are none here. Gelman Decl. ¶¶ 11-13. In response to Dr. Federgruen's argument that DOHMH should have used Israeli data, Dr. Gelman argued that "there are enough differences between the countries that it makes the most sense" to use only U.S. data; the Department "cannot just pool unconnected data." Id. ¶ 16. Finally, with regard to plaintiffs' experts' criticism of the MMWR Study's methodology for calculating confidence intervals, Dr. Farley noted that even using a Poisson distribution, advocated by Dr. Federgruen, Federgruen Aff. II ¶ 18(a); see also Zucker Decl. ¶ 9, the

association between MBP and HSV-1 would remain statistically significant. Farley Decl. ¶ 53 (reporting that the 95% confidence interval using a Poisson distribution is 1.2 – 6.0, which is statistically significant because it is entirely above 1.0).

In short, there are disagreements between the parties regarding the MMWR Study. As established below, however, we need not resolve these disagreements because we deny plaintiffs' motion for a preliminary injunction without relying on the MMWR Study.

III. Discussion

A. Legal Standard

Under Second Circuit precedent, a party seeking a preliminary injunction must establish "(a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief." Christian Louboutin S.A. v. Yves Saint Laurent Am. Holdings, Inc., 696 F.3d 206, 215 (2d Cir. 2012) (quoting UBS Fin. Servs., Inc. v. W. Va. Univ. Hosps., Inc., 660 F.3d 643, 648 (2d Cir. 2011)) (internal quotation marks omitted). "When, as here, the preliminary injunction 'will affect government action taken in the public interest pursuant to a statutory or regulatory

scheme,' it 'should be granted only if the moving party meets the more rigorous likelihood-of-success standard." Red Earth LLC v. United States, 657 F.3d 138, 143 (2d Cir. 2011) (quoting Metro. Taxicab Bd. of Trade v. City of New York, 615 F.3d 152, 156 (2d Cir. 2010)). The party seeking a preliminary injunction must also demonstrate "that the public's interest weighs in favor of granting an injunction." Id. (quoting Metro. Taxicab Bd. of Trade, 615 F.3d at 156) (internal quotation mark omitted). When a party challenges a law on its face, rather than as applied, the party "must establish that no set of circumstances exists under which the [law] would be valid." Arizona v. United States, 132 S. Ct. 2492, 2534 (2012) (quoting United States v. Salerno, 481 U.S. 739, 745 (1987)) (internal quotation mark omitted).

With regard to irreparable harm, "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71 (2d Cir. 1996) (quoting Elrod v. Burns, 427 U.S. 347, 373 (1976)) (internal quotation marks omitted). The Second Circuit has presumed irreparable harm in the contexts of compelled speech, see, e.g., id., and free exercise of religion, see, e.g., Jolly v. Coughlin, 76 F.3d 468, 482 (2d Cir. 1996). Here, if plaintiffs establish a likelihood of success on the merits on either their compelled

speech claim or their free exercise claim, irreparable injury will be presumed.

Finally, although a motion for a preliminary injunction "should not be resolved on the basis of affidavits which evince disputed issues of fact," Charette v. Town of Oyster Bay, 159 F.3d 749, 755 (2d Cir. 1998) (quoting Forts v. Ward, 566 F.2d 849, 851 (2d Cir. 1977)) (internal quotation marks omitted), "[a]n evidentiary hearing is not required when the relevant facts . . . are not in dispute," id. Here, for the reasons discussed below, we can resolve plaintiffs' motion for a preliminary injunction without relying on any disputed facts, and thus we need not conduct an evidentiary hearing prior to ruling on the motion.

B. Free Speech

Plaintiffs' first argument is that section 181.21 compels speech in violation of the First Amendment. The Free Speech Clause of the First Amendment, incorporated against the states by the Fourteenth Amendment, Gitlow v. New York, 268 U.S. 652, 666 (1925), provides: "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The Supreme Court has established that "one important manifestation of the principle of free speech is that one who chooses to speak may also decide 'what not to say.'" Hurley v. Irish-Am. Gay, Lesbian and Bisexual Group of Boston, 515 U.S. 557, 573 (1995)

(quoting Pac. Gas and Elec. Co. v. Pub. Utils. Comm'n of Cal., 475 U.S. 1, 16 (1986)). According to plaintiffs, section 181.21 abrogates this rule by "compel[ling] mohelim to pass along the Department's 'advice' against MBP." Pls.' Mot. 5. Plaintiffs contend that the regulation would therefore need to satisfy strict scrutiny, a test which, according to plaintiffs, the regulation fails. Id. at 5-9.

The flaw in plaintiffs' argument is that it flatly misreads the regulation. The regulation imposes two obligations on mohels: first, they must "obtain[]" written informed consent from a parent prior to performing MBP and second, they "must give the parent or legal guardian a copy of the signed consent form and retain the original for one year from the date of the circumcision, making it available for inspection if requested by the Department." Notice of Adoption, Sept. 21, 2012, at 2600. Plaintiffs conceded at oral argument that the second obligation, giving the parent a copy of the signed consent form and retaining the original, does not compel speech. Tr. 41-42. Plaintiffs' compelled speech argument therefore rests wholly on the requirement that mohels, prior to performing MBP, "obtain[]" written consent using either a form distributed by DOHMH or a different form meeting certain minimum requirements.

Nowhere in the regulation are mohels required to provide a consent form to parents or even to inform parents that such a

form exists. Assuming that the consent form prepared by DOHMH is made available on the Department's website, as Dr. Varma suggested it would be, parents would be able to obtain the form themselves and give the signed form to the mohel without any communicative action by the mohel. Presumably, DOHMH could also seek to distribute its forms at hospitals or pediatricians' offices. Given that the regulation is not yet in force, we do not presently know whether DOHMH will employ one or more of these methods to disseminate its consent form. However, because plaintiffs' facial challenge requires that section 181.21 be valid under "no set of circumstances," Arizona, 132 S. Ct. at 2534 (quoting Salerno, 481 U.S. at 745), it is sufficient for present purposes that more than one plausible set of circumstances exists in which the Department would distribute consent forms online or through other avenues that did not involve communicative action by the mohels.

It should be remembered, of course, that although plaintiffs here are exclusively mohels and organizations representing mohels, mohels are not the only persons with an interest in having MBP performed. Rather, parents who seek a bris involving MBP likely feel, for religious or other reasons, that having MBP performed is deeply important. Thus, it is reasonable to expect that at least some of those parents seeking a mohel who regularly performs MBP, and possibly most such

parents, will have an incentive to obtain a consent form themselves and present a completed copy to the mohel. With sufficient outreach by DOHMH, moreover, obtaining a consent form prior to the day of circumcision will not require significant effort, but may be as easy as picking up a form at a pediatrician's office or visiting a website referenced in a community mailing.

Plaintiffs respond that "at the end of the day, the regulation imposes a requirement on the mohel to obtain the consent form, and if, for whatever reason, the parent did not have the consent form ready to go, the mohel would be required to give it to them, thus communicating the government's message." Tr. 38. Not so. If a parent arrived with her infant on the day of the bris and did not have a consent form, section 181.21 would simply require that the mohel not perform MBP until the parent somehow procured a consent form, signed it, and gave it to the mohel. Nothing in the regulation would require the mohel to provide the consent form himself. Indeed, if a mohel fundamentally objected to the Department's consent form and to the language required to be included on other consent forms, and it was (counterfactually) impossible for the parent to obtain a consent form independently, the mohel would still be free not to say anything or otherwise to undertake any communicative act. He simply could not perform MBP. That situation undoubtedly

would raise a free exercise issue, as the mohel's ability to practice a religious ritual would have been burdened, but there would be no compelled speech.[13]

At oral argument, plaintiffs sought to revive the compelled speech issue by invoking a note published in The City Record following the regulation itself. Tr. 37. The note reads:

> [Section] 181.21 was added to Article 181 by resolution adopted September 13, 2012 to require that persons who perform circumcisions on infants under one year of age that include the application of direct oral suction obtain the written consent of a parent prior to performance of the circumcision and warn the parent of the Department's concerns about the risks of infection posed by direct oral suction.

Notice of Adoption, Sept. 21, 2012, at 2600 (emphasis added). Recognizing that the note itself is not law, plaintiffs argued that the note would nonetheless "be instructive about how the regulation is supposed to be interpreted." Tr. 37.

This argument is to no avail. Under "settled principles of statutory construction," courts "must first determine whether the statutory text is plain and unambiguous," and, if it is, "must apply the statute according to its terms." Corley v. United States, 556 U.S. 303, 323-24 (2009) (quoting Carcieri v. Salazar, 555 U.S. 379, 387 (2009)) (internal quotation marks

[13] It is immaterial that mohels might choose to carry extra consent forms or at least direct parents to websites containing such forms. Although mohels would be free to do either of these things, possibly as a service to parents or to expedite their own fulfillment of religious duties, section 181.21 does not require them to do so.

omitted). Here, although the note might suggest some confusion among defendants' staff regarding what the regulation requires, the regulation's text is "plain and unambiguous": a mohel must "obtain[]" a signed consent form prior to performing MBP but need not provide the form himself or even acknowledge the form's existence. Accordingly, for purposes of plaintiffs' compelled speech argument, our interpretation of section 181.21 begins and ends with the regulation's text. The text of section 181.21 does not compel speech, thus plaintiffs are unlikely to prevail on their claim that the regulation violates their rights under the First Amendment's Free Speech Clause.

C. Free Exercise of Religion

Plaintiffs' second argument is that section 181.21 violates their rights to free exercise of religion under the federal Constitution's First Amendment and under article I, section 3 of the New York State Constitution. We will address these arguments in turn.

1. Free Exercise Under the First Amendment

The Free Exercise Clause of the First Amendment, applied against the states by incorporation into the Fourteenth Amendment, see Cantwell v. State of Connecticut, 310 U.S. 296, 303 (1940), provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." U.S. Const. amend. I (emphasis added). As plaintiffs

and defendants agree, the governing federal free exercise decisions are Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520 (1993), and Employment Division v. Smith, 494 U.S. 872 (1990).

In Lukumi, a Santeria church sought to open a house of worship at which ritual animal sacrifice would regularly be performed. Lukumi, 508 U.S. at 525-26. After the church had leased land in the City of Hialeah, the city council passed a series of ordinances that prohibited animal sacrifices, using language that applied to Santeria ritual sacrifice but that excluded several other forms of animal killing. Id. at 527-28. The Court invalidated the ordinances, holding that they unconstitutionally restricted plaintiffs' free exercise rights.

The Lukumi Court first established the basic standards applicable to free exercise claims. The Court explained: "[A] law that is neutral and of general applicability need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice." Id. at 531. By contrast, "[a] law failing to satisfy these requirements must be justified by a compelling governmental interest and must be narrowly tailored to advance that interest." Id. at 531-32.

With regard to neutrality, the Court reasoned that, "[a]t a minimum, the protections of the Free Exercise Clause pertain if

the law at issue discriminates against some or all religious beliefs or regulates or prohibits conduct because it is undertaken for religious reasons." Id. at 532. The Court elaborated that, "[a]lthough a law targeting religious beliefs as such is never permissible, if the object of a law is to infringe upon or restrict practices because of their religious motivation, the law is not neutral" and is therefore subject to strict scrutiny. Id. at 533 (internal citations omitted).

To determine whether a law is neutral, a court "must begin with its text, for the minimum requirement of neutrality is that a law not discriminate on its face." Id. "A law lacks facial neutrality if it refers to a religious practice without a secular meaning discernable from the language or context." Id. The Lukumi Court found that the text of the ordinances at issue was facially neutral because, even though the ordinances used the words "sacrifice" and "ritual," these words have common secular meanings as well as religious ones, and the word "sacrifice" was explicitly defined by the ordinances in secular terms. Id. at 533-34.

The inquiry, of course, does not end there, as "[t]he Free Exercise Clause protects against governmental hostility which is masked, as well as overt." Id. at 534. "The Court must survey meticulously the circumstances of governmental categories to eliminate, as it were, religious gerrymanders." Id. (quoting

Walz v. Tax Comm'n of NYC, 397 U.S. 664, 696 (1970) (Harlan, J., concurring)). Evaluating the ordinances passed by the City of Hialeah, the Court concluded that they failed the neutrality test. For one, their use of the words "sacrifice" and "ritual," though not automatically violative of facial neutrality, did suggest that the ordinances' object was to restrict the exercise of religion. Id. at 534. Moreover, one of the ordinances had explicitly expressed concern about practices that might be engaged in by "certain religions," which in context clearly referred only to Santeria. Id. at 534-35.

In addition to its text, "the effect of a law in its real operation is strong evidence of its object." Id. at 535. The Court clarified that "adverse impact will not always lead to a finding of impermissible targeting," as "a social harm may have been a legitimate concern of government for reasons quite apart from discrimination." Id. The question is whether the circumstances as a whole "disclose an object remote from these legitimate concerns." Id.

Three of the ordinances in Lukumi did have such an impermissible object. The first ordinance prohibited animal sacrifice, defining sacrifice as "to unnecessarily kill . . . an animal in a public or private ritual or ceremony not for the primary purpose of food consumption." Id. at 535-36. The Court observed that "careful drafting" of this ordinance had "ensured

that, although Santeria sacrifice is prohibited, killings that are no more necessary or humane in almost all other circumstances are unpunished." Id. at 536. In other words, because the ordinance was underinclusive, regulating conduct motivated by the Santeria faith but not secular conduct that implicated the same legitimate governmental interests, the Court concluded that the law targeted Santeria itself. Id.

The second ordinance prohibited the "possess[ion], sacrifice, or slaughter" of an animal with the "inten[t] to use such animal for food purposes." Id. at 536. The ordinance applied only if an animal was killed in a "ritual," and it exempted "any licensed [food] establishment" with respect to "any animals which are specifically raised for food purposes," if the activity was permitted by zoning and other laws. Id. The Court found in this ordinance "[a] pattern of exemptions [that] parallel[ed] the pattern of narrow prohibitions" in the first ordinance. Id. at 537. These exemptions, which would permit, for instance, kosher slaughter, "contribute[d] to the gerrymander" whereby Santeria sacrifice was targeted for regulation while other animal killing was not. Id.

Finally, the third ordinance incorporated the language of the state animal cruelty statute, which prohibited "unnecessarily . . . kill[ing] any animal" and was interpreted by the City to forbid religious animal sacrifice but not

"hunting, slaughter of animals for food, eradication of insects and pests, and euthanasia." Id. The Court found that the City's interpretation of the ordinance "devalues religious reasons for killing by judging them to be of lesser import than nonreligious reasons," thus "singl[ing] out" religious practice for discriminatory treatment. Id. at 537-38.

The Court found further evidence of the ordinances' lack of neutrality "in the fact that they proscribe more religious conduct than is necessary to achieve their stated ends." Id. at 538. To further the public health interest in preventing improper disposal of animal carcasses, the City did not need to ban all Santeria sacrificial practice, but rather "could have imposed a general regulation on the disposal of organic garbage." Id. Thus, the ordinances "prohibit[ed] Santeria sacrifice even when it d[id] not threaten the city's interest in the public health." Id. at 538-39. To further the public interest in preventing cruelty to animals, the City could have directly regulated animals' "conditions and treatment" or "method of slaughter." Id. at 539. Because of these "'gratuitous restrictions' on religious conduct," id. at 538 (quoting McGowan v. Maryland, 366 U.S. 420, 520 (1961) (Frankfurter, J., concurring)), the Court inferred that the ordinances sought "not to effectuate the stated governmental interests, but to suppress the conduct because of its religious

motivation." Id. at 538. In light of all of this evidence, the Court concluded that "[t]he ordinances had as their object the suppression of religion" and thus were not neutral. Id. at 542.

The Lukumi Court then considered whether the regulation was generally applicable. This requirement embodies "[t]he principle that government, in pursuit of legitimate interests, cannot in a selective manner impose burdens only on conduct motivated by religious belief." Id. at 543.

The ordinances enacted by the City of Hialeah were not generally applicable because they were underinclusive with respect to the legitimate governmental interests they purportedly advanced.[14] In other words, the ordinances "fail[ed] to prohibit nonreligious conduct that endangers these interests in a similar or greater degree than Santeria sacrifice does." Id. With regard to preventing cruelty to animals, the ordinances permitted numerous activities that were at least as cruel to animals as Santeria sacrifice, such as fishing, euthanasia of unwanted animals, and extermination of mice and rats. Id. at 543-44. With regard to preventing the improper disposal of animal carcasses, the ordinances did nothing to

[14] As the Lukumi Court's analysis of neutrality demonstrates, a law's underinclusiveness with respect to its purported secular objects is also an indicator that the law in fact pursues discriminatory rather than secular objects. This overlap between the neutrality and general applicability requirements is consistent with the Court's observation that the two requirements "are interrelated, and . . . failure to satisfy one requirement is a likely indication that the other has not been satisfied." Lukumi, 508 U.S. at 531.

regulate how hunters dispose of their kill or how restaurants dispose of garbage including animal remains. Id. at 544-45. Finally, with regard to preventing harms associated with the consumption of uninspected meat, the ordinances did not regulate hunters' or fishermen's ability to eat what they bring in without undergoing a governmental inspection. Id. at 545. The Court concluded that "each of Hialeah's ordinances pursue[d] the city's governmental interests only against conduct motivated by religious belief." Id. The ordinances "ha[d] every appearance of a prohibition that society is prepared to impose upon [Santeria worshippers] but not upon itself," id. (quoting Florida Star v. B.J.F., 491 U.S. 524, 542 (1989) (Scalia, J., concurring in part and concurring in the judgment)) (second alteration in original) (internal quotation marks omitted) -- the "precise evil [that] the requirement of general applicability is designed to prevent," id. at 546. For the independent reasons that the ordinances were not neutral and not generally applicable, the Court applied strict scrutiny and found that the regulations failed this test. Id. at 546-47.

The Court's decision in Lukumi contrasts with its decision three years earlier in Employment Division v. Smith, 494 U.S. 872 (1990). In Smith, two employees of a private drug rehabilitation organization were fired after ingesting peyote in violation of an Oregon statute that criminalized possession of

controlled substances, including peyote. Id. at 874. The employees had ingested the peyote for sacramental purposes at a ceremony of the Native American Church. Id. When they applied for state unemployment compensation, their claims were denied because they had been fired for work-related "misconduct." Id. The Supreme Court upheld the state unemployment division's decision, ruling that it was neutral and generally applicable.

The Smith Court began by rejecting the proposition that "an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate." Id. at 878-79. In other words, the First Amendment does not allow an individual to object to a "valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)." Id. at 879 (quoting United States v. Lee, 455 U.S. 252, 263, n.3 (1982) (Stevens, J., concurring)) (internal quotation marks omitted).

In that case, the Court found that the Oregon criminal law at issue was neutral and generally applicable. There was "no contention that Oregon's drug law represent[ed] an attempt to regulate religious beliefs," and the "otherwise prohibitable conduct" prescribed by the law was not shielded by the First Amendment merely because it was "accompanied by religious convictions." Id. at 882. Therefore, even though the law

incidentally burdened the exercise of religion, it did not run afoul of the First Amendment. Id.

Although the Smith Court did not state that it was applying rational basis review, subsequent decisions have understood Lukumi and Smith to establish that rational basis review applies to a neutral and generally applicable law challenged on free exercise grounds. See, e.g., Commack Self-Service Kosher Meats, Inc. v. Hooker, 680 F.3d 194, 212 (2d Cir. 2012) ("[W]hen the government seeks to enforce a law that is neutral and generally applicable, 'it need only demonstrate a rational basis for its enforcement, even if enforcement of the law incidentally burdens religious practices.'" (quoting Fifth Ave. Presbyterian Church v. City of New York, 293 F.3d 570, 574 (2d Cir. 2002))).

Here, section 181.21 is distinguishable from the ordinances in Lukumi and analogous to the criminal law in Smith. We begin with neutrality. As the Lukumi Court instructed, the neutrality inquiry starts with the law's text. On its face, section 181.21 is neutral because it does not explicitly refer to a religious practice, and does not even use religious words as the ordinances in Lukumi did. Although there are no known instances other than MBP in which direct oral suction during circumcision is practiced, the facial neutrality test is satisfied because the language of the regulation is secular.

Looking to other indicia of neutrality, although the legislative history of section 181.21 focuses explicitly on MBP, the operation of the statute is neutral. Unlike Lukumi, this is a case where societal harms, namely neonatal HSV-1 infection and the undermining of parents' ability to make informed decisions about protecting their children's health, are "legitimate concern[s] of government for reasons quite apart from discrimination." Lukumi, 508 U.S. at 535. Prior to approving the proposed regulation, the Board of Health received several letters from national medical organizations warning that MBP posed a grave risk of HSV-1 transmission to infants, as well as peer-reviewed studies from 2000, 2003, and 2004 confirming this risk and complaints from parents that MBP had been performed on their children without their knowledge or consent. The Board therefore had strong reason to believe that MBP as then-practiced was threatening infants' health and parents' right to make informed decisions about how to care for their children. In the course of this litigation, moreover, the amicus submission on behalf of four respected national medical organizations and the testimony of numerous highly prominent infectious disease experts have provided further evidence that MBP poses a serious risk of HSV-1 transmission.[15] Therefore, it

[15] As discussed above, plaintiffs have not attacked these organizations' and experts' credibility or qualifications to evaluate the medical risk posed by MBP.

is clear that MBP implicates defendants' legitimate governmental interests in safeguarding children's health and protecting parents' right to make informed decisions about their children's care, and the informed consent requirement established in section 181.21 plainly furthers these interests.[16]

Not only does the regulation have several valid secular objects, but there is also no indication in the record that it has a discriminatory object against religion in general or Judaism in particular. DOHMH's extensive educational outreach regarding the risks of MBP, starting in 2005 and continuing through the present, suggests that the Department is genuinely concerned about the risk of HSV-1 transmission. Viewed in the context of this educational outreach, the present regulation appears to be one component of a long-term, multifaceted strategy to reduce the incidence of neonatal herpes and promote informed parental decisionmaking.

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[16] The fact that professional medical standards of sterility would prohibit physicians from engaging in orogenital contact during circumcision, see Farley Decl. ¶ 7; Kimberlin Aff. ¶ 7, offers additional support for our finding that the regulation furthers the governmental interest in protecting children's health. Even if plaintiffs are correct that the legal standards governing regulation of physicians do not apply to the regulation of MBP, the fact remains that the orogenital contact involved in MBP has been recognized by the medical profession to be unsafe and to create a serious risk of infection. See Farley Decl. ¶ 7; Kimberlin Aff. ¶ 7. It follows that the public health interest asserted by the government to justify section 181.21, far from being a screen for discrimination, is in fact a legitimate governmental interest genuinely triggered by MBP. The same concern for protecting children's health that has led the medical establishment to develop standards of sterility during circumcisions, standards that would preclude orogenital contact, has also led defendants to adopt the regulation at issue.

One indicator that a law is not neutral is if it is underinclusive, regulating religious conduct while failing to regulate secular conduct that is at least as harmful to the legitimate governmental interests purportedly justifying the law. Lukumi, 508 U.S. at 535-38. In Lukumi, the ordinances prohibited Santeria sacrifice while allowing numerous secular practices that were at least as harmful to the ordinances' purported legitimate objects, such as preventing cruelty to animals. Id. Here, on their motion for a preliminary injunction, plaintiffs bear the burden of articulating particular secular conduct that defendants should have regulated but did not. See Christian Louboutin S.A. v. Yves Saint Laurent Am. Holdings, Inc., 696 F.3d 206, 215 (2d Cir. 2012). Plaintiffs seek to discharge this burden by suggesting that DOHMH should have "address[ed] the risks of contact with other breaks in infants' skin, outside the circumcision context." Pls.' Reply Mem. of Law in Supp. of Pls.' Mot. for a Prelim. Inj. 13 [hereinafter Pls.' Reply]. At oral argument, plaintiffs similarly argued that HSV-1 transmission from saliva to an open wound is "not necessarily something that would happen only through the metzitzah b'peh[; h]erpes can be transmitted through all sorts of household contact, such as a mother infected with herpes who has a cut and transmits blood to an open wound on an infant." Tr. 11. However, although these arguments posit

theoretical categories of regulation that defendants could possibly pursue, they do not point to specific conduct that the Board of Health could practically have regulated but did not. Moreover, plaintiffs do not demonstrate that the risk posed by any such particular, regulable conduct is comparable to the risk posed by MBP. Although plaintiffs have offered hazy speculation that there might exist some regulable activity during which a caregiver's blood or saliva might come in contact with an infant's open wound and thereby might cause a risk of HSV-1 transmission comparable to that posed by MBP, this speculation does not discharge plaintiffs' burden of proof.

Plaintiffs also argue that DOHMH should have acted "to protect infants with non-MBP circumcisions from infection." Pls.' Reply 13. However, with regard to circumcisions performed in a hospital or other medical setting, professional medical standards already require a sterile environment and prohibit conduct, such as direct oral suction, that exposes the wound to pathogens. Farley Decl. ¶ 7; Kimberlin Aff. ¶ 7. With regard to circumcisions performed in a non-medical setting, plaintiffs' argument fails because plaintiffs do not allege any specific element of non-MBP circumcision that exposes infants to a risk of HSV-1 infection similar to that posed by MBP and which could practically be regulated. In other words, plaintiffs have not pointed to specific comparable conduct that defendants should

have regulated, and thus they fail to raise an inference that the regulation has a discriminatory object.

With regard to the eighty-five percent of neonatal HSV-1 cases transmitted by mothers to infants during the birth process, plaintiffs' suggestion takes a more defined form, but nevertheless fails for other reasons. Plaintiffs note that caesarean delivery significantly reduces the risk of HSV-1 transmission during birth and ask why DOHMH did not require warnings "before every vaginal birth, advising caesarean delivery." Pls.' Reply 13.[17] This argument fails on several levels. First, defendants do not have the authority to regulate patient care within hospitals. See N.Y. Pub. Health Law §§ 2800, 2812 (McKinney 2012); see also Bd. of Health Meeting Tr., Sept. 13, 2012, at 113. The Board of Health therefore would not have had authority to mandate that hospitals (or doctors operating therein) provide warnings "before every

[17] It is already established medical practice to perform a c-section if a woman is presently experiencing symptoms of genital HSV. Tr. 13-14; Farley Decl. ¶ 13 ("Because neonatal herpes is so serious, the American College of Obstetrics and Gynecologists recommends that cesarean section delivery be performed if a pregnant woman has any signs of genital herpes at the time of delivery."). Therefore, contrary to plaintiffs' suggestion, there was no need for DOHMH to "warn, regulate, or advise in favor of cesarean sections where a mother is symptomatic." Tr. 12. We read plaintiffs' argument to focus on when a mother is not experiencing HSV-1 symptoms, a situation in which, as both parties agree, (1) most mothers will in fact be infected with HSV-1, albeit not necessarily genital HSV-1, and (2) an infected, asymptomatic mother who acquired HSV-1 during her last trimester of pregnancy may infect her child during the birth process. Tr. 4, 12-13; Farley Decl. ¶¶ 10, 13.

vaginal birth," and the Board's failure to do so is not evidence of any discriminatory object.

Second, even if defendants had authority to mandate that hospitals recommend c-sections to all women, plaintiffs have not shown that such advice would further the government's public health interest in a manner similar to requiring informed consent before MBP. Even if the rate of HSV-1 transmission during birth were comparable to the rate of HSV-1 transmission from MBP, c-sections are serious surgical procedures that involve obvious medical risks to the mother. This is not to devalue the religious benefits of MBP, but rather simply to observe that the Board of Health could have reasonably concluded that warning against MBP yields substantially greater public health benefits, and creates substantially fewer public health risks, than suggesting that women routinely undergo c-sections. In other words, to show a discriminatory object, plaintiffs would need to demonstrate that a hypothetical DOHMH recommendation that all women undergo c-sections would, on balance, have furthered the governmental interest in public health at least as much as a warning against MBP. Plaintiffs have failed to make such a showing. Not to forget, of course, that the Board of Health does not have authority in the first place to require hospitals to perform, recommend, or advise about c-sections.

At oral argument, plaintiffs additionally suggested:

> [T]he city could have undertaken a broader educational campaign in order to inform people -- parents, caretakers, nannies, others -- about the risks of transmitting herpes from even asymptomatic individuals to infants through some sort of open wound and could have undertaken a broader educational campaign, not just targeted at MBP in order to explain the mode of transmission and how it can be prevented.

Tr. 11-12. However, it seems that DOHMH already does this to some extent: defendants explained at oral argument that "the Department of Health has physicians on staff that go and provide grand rounds and lecture on these issues, as well as all kinds of preventative strategies such as, for example, refraining from sexual contact at the end of the third trimester of pregnancy, among other things." Tr. 13. Moreover, this suggestion, like the suggestions above, reveals its lack of substance when examined more closely. Eighty-five percent of neonatal herpes cases are caused by transmission during birth, generally by asymptomatic mothers because otherwise a c-section would likely have been performed. These mothers might not even know that they are infected with HSV-1. Assuming nonetheless that the mothers would respond to education regarding the risk of HSV-1 transmission, plaintiffs do not suggest what education DOHMH could usefully have provided beyond advising pregnant women, as it currently does, to avoid sexual conduct at the end of pregnancy in order to minimize the chance that the baby will be

exposed to herpes virus without maternal antibodies. It certainly is not obvious, for the reasons discussed above, that all pregnant women should be advised to undergo c-sections, and plaintiffs do not suggest other educational messages that DOHMH should have provided.

With regard to the remaining fifteen percent of neonatal herpes cases, plaintiffs' suggestion of "broader education" is also not helpful. Five percent of cases involve congenital transmission (in utero), and here, as with transmission during birth, it is not clear what education the Department should have provided beyond its current advice to avoid conduct that increases the risk of transmitting virus to the baby without maternal antibodies. The final ten percent of cases involve postnatal transmission (after birth). As discussed above in the context of plaintiffs' "household transmission" argument, plaintiffs have not articulated any specific activity that puts infants at a risk of HSV-1 infection similar to that posed by MBP and therefore have not shown what advice DOHMH could have given to parents but did not.

As a catch-all argument, plaintiffs contend that DOHMH "should have taken some action, if its concern was with the spread of neonatal herpes, to address the sources and potentially prevention of the other 79 out of the 84 cases that it identified in the 5.75-year period [from April 2006 to

December 2011]." Tr. 11; see also Tr. 13, 18. Despite this argument's rhetorical appeal, however, it fails to satisfy plaintiffs' burden to show a discriminatory object. Particularly with regard to the strong majority of neonatal herpes cases resulting from transmission during birth, the Department's options for additional regulation are limited, given that the Department does not have authority to regulate the medical care mothers receive at hospitals or the information hospitals provide to them. Nonetheless, defendants have undertaken educational outreach regarding ways to reduce the risk that mothers will transmit HSV-1 to their children. It is also significant that the Department has pursued several educational outreach initiatives regarding the risk of HSV-1 transmission through MBP. Although these initiatives focus on MBP, they are still examples of other action the Department has taken to further its legitimate ends of protecting children's health and informed parental decisionmaking without burdening religious practice. Finally, although there are undoubtedly a number of possible means of HSV-1 transmission that the Department did not regulate, it is plaintiffs' burden, on their motion for a preliminary injunction, to articulate with some specificity what additional regulations defendants could have enacted to further their legitimate interests. Christian Louboutin S.A. v. Yves Saint Laurent Am. Holdings, Inc., 696

F.3d 206, 215 (2d Cir. 2012). The absence of such meaningful allegations suggests that the regulation does not have a discriminatory object.

Not only do plaintiffs fail to adduce proof of a discriminatory object through underinclusiveness, but they also fail to show a discriminatory object through overinclusiveness. Section 181.21 is plainly not overinclusive. The regulation does not ban MBP, does not impose costly burdens on mohels' practice of MBP, and does not regulate how mohels perform MBP. Indeed, as discussed above in the context of compelled speech, the regulation does not even require mohels to give parents a consent form or to discuss with them the risk of HSV-1 transmission. All that the regulation requires is that mohels "obtain[]" a signed consent form prior to performing MBP, return a copy to a parent, and keep the form for a year after the circumcision. Had the regulation required any less, it would not have ensured that parents are aware of and consent to MBP before it is performed on their child, nor would it have provided a way for DOHMH to verify that consent. Merely distributing educational materials at hospitals would not alert parents that MBP will be performed on their child and would not allow them an opportunity to provide or withhold consent.

At oral argument, plaintiffs suggested that section 181.21 is nonetheless overinclusive because the required warning

includes the Department's advice against performing MBP, advice which is not necessary to inform parents that MBP will be performed and which can be transmitted through the less burdensome method of educational outreach. Tr. 26-27. However, distribution of the Department's advice regarding MBP to parents through educational outreach, such as through the Before the Bris (2012) brochure, is plainly not as effective as including it on a form that parents must sign prior to a circumcision. For one, including information on a short form that parents must sign increases the chance that they will read and consider it, in contrast to simply mailing the information to parents or including it within what is likely a large bundle of information that new parents receive at the hospital. Additionally, the Department does not have the ability to ensure that all new parents receive the Before the Bris (2012) brochure. The Department's agreement with hospitals covers only "a small number of New York City hospitals," Tr. 29, and the Department does not have the authority to require that other hospitals distribute the brochure or even that hospitals within the agreement abide by their commitment, see N.Y. Pub. Health Law §§ 2800, 2812. Therefore, plaintiffs cannot demonstrate that here, as was the case in Lukumi, the regulation burdens more religious conduct than is necessary to further the government's legitimate purposes.

In sum, section 181.21 does not accomplish a "religious gerrymander[]" through underinclusiveness, Lukumi, 508 U.S. at 534 (quoting Walz v. Tax Comm'n of NYC, 397 U.S. 664, 696 (1970) (Harlan, J., concurring)), nor does it impose "'gratuitous restrictions' on religious conduct" through overinclusiveness, id. at 538 (quoting McGowan v. Maryland, 366 U.S. 420, 520 (1961) (Frankfurter, J., concurring)). We therefore cannot conclude that the regulation "ha[s] as [its] object the suppression of religion." Id. at 542. Rather, as in Smith, the law furthers legitimate governmental interests implicated by the regulated conduct; it does not target the conduct's underlying religious motivation. See Smith, 494 U.S. at 882. Accordingly, we find that the regulation is neutral.

The next issue is whether section 181.21 is generally applicable -- the requirement that laws not selectively pursue legitimate ends against only conduct motivated by religious belief. Lukumi, 508 U.S. at 543. Here, as discussed above, plaintiffs have not shown that the regulation is underinclusive. Although defendants possess limited power under state law to regulate childbirth, they have pursued educational initiatives regarding the risk of HSV-1 transmission by mothers and by mohels. Plaintiffs have not pointed to specific other activities defendants could have regulated that pose a risk of HSV-1 transmission similar to that posed by MBP. Therefore, in

contrast to the ordinances in Lukumi and similar to the law in Smith, section 181.21 is not underinclusive, but rather is generally applicable. Because the regulation is neutral and generally applicable and only incidentally burdens a religious practice, the regulation is subject to rational basis review. See Smith, 494 U.S. at 882; Commack Self-Service Kosher Meats, Inc. v. Hooker, 680 F.3d 194, 212 (2d Cir. 2012).

Plaintiffs cite three decisions to support their argument that strict scrutiny applies, but each is distinguishable. First, plaintiffs cite Shrum v. City of Coweta, 449 F.3d 1132 (10th Cir. 2006). In Shrum, a police officer who was also a clergyman had his work schedule rearranged by the Chief of Police, such that the officer's work schedule conflicted with his religious duties. Id. The Tenth Circuit held that the Chief's actions violated the officer's free exercise rights. Id. Although the Chief's aim was the secular one of forcing the officer out of his job, the Chief furthered this end through religiously discriminatory means, namely imposing a work schedule with the object of burdening the officer's exercise of religion. Id. at 1144. The Chief decided to rearrange the officer's schedule "precisely because of [the Chief's] knowledge of [the officer's] religious commitment." Id. Here, by contrast, the object of the regulation is not to burden the mohels' exercise of religion, but rather to further the societal

ends of safeguarding children's health and protecting parents' right to make informed decisions in caring for their children. Given that the regulation is neither underinclusive nor overinclusive, that there is extensive evidence of defendants' attempts to address the risk of HSV-1 transmission in less intrusive ways, and that the regulation itself allows MBP to continue in its traditional form, the regulation cannot be said to have as its object discrimination against religion.

Plaintiffs also cite Midrash Sephardi, Inc. v. Town of Surfside, 366 F.3d 1214 (11th Cir. 2004). In Midrash Sephardi, the Eleventh Circuit held that a zoning ordinance that prohibited two synagogues from erecting buildings in a town's business district violated the synagogues' right to free exercise of religion. Id. The ordinance was underinclusive because it failed to prohibit private clubs from building in the business district although private clubs undermined the asserted governmental interest in promoting commercial activity. Id. at 1232-35. The ordinance was also overinclusive because synagogues, the record demonstrated, actually promoted commercial activity. Id. This evidence suggested that the town "improperly excluded religious assemblies because of their religiosity." Id. at 1234. Here, by contrast, plaintiffs have failed to demonstrate that the regulation is either overinclusive or underinclusive, and the evidence indicates that

the object of requiring informed consent was not to target the Jewish motivation behind MBP, but rather to protect children's health and their parents' ability to make informed decisions regarding their care.

Finally, plaintiffs cite Grossbaum v. Indianapolis-Marion County Building Authority, 100 F.3d 1287 (7th Cir. 1996). In Grossbaum, a local rule prohibited private groups and individuals from exhibiting displays in the lobby of a government building. Id. In the course of upholding this rule, the Seventh Circuit reasoned:

> A regulation that prohibited all private groups from displaying nine-pronged candelabra may be facially neutral, but it would still be unconstitutionally discriminatory against Jewish displays. The lack of general applicability is obvious not from the government's motives but from the narrowness of the regulation's design and its hugely disproportionate effect on Jewish speech.

Id. at 1298 n.10. Here, plaintiffs' clear implication is that section 181.21, like the regulation speculated about in Grossbaum, is impermissible because it applies only to MBP and has a "hugely disproportionate effect" on Jewish free exercise. However, not only is this statement dicta, indeed dicta from a different circuit, but the regulation it envisages prohibiting nine-pronged candelabra is readily distinguishable. There is no apparent nonreligious reason to prohibit nine-pronged candelabra but not eight-pronged candelabra or other similar light fixtures

that would pose similar harms. It would seem that the only object of prohibiting nine-pronged candelabra alone would be to target their underlying use in or association with Jewish religious practice. In other words, this regulation would be problematic not simply because it focused on a Jewish ritual object, but rather because it focused on a Jewish ritual object while underinclusively failing to regulate other objects that implicate the same legitimate governmental ends. In our case, by contrast, although the regulation focuses on a single religious practice, plaintiffs have not articulated comparable conduct that defendants should have regulated, and indeed defendants enacted the regulation only after pursuing several educational initiatives that sought to combat HSV-1 transmission without burdening religious practice.

Having concluded that section 181.21 is neutral and generally applicable, we apply rational basis review. Under this standard of review, "legislation is presumed to be valid and will be sustained if the [burden imposed] by the statute is rationally related to a legitimate state interest." Town of Southold v. Town of East Hampton, 477 F.3d 38, 54 (2d Cir. 2007) (quoting City of Cleburne v. Cleburne Living Ctr., 473 U.S. 432, 440 (1985)) (internal quotation marks omitted). A law will be upheld "if there is any reasonably conceivable state of facts that could provide a rational basis for the [burden imposed]."

Heller v. Doe by Doe, 509 U.S. 312, 320 (1993) (quoting FCC v. Beach Commn'ns, Inc., 508 U.S. 307, 313 (1993)) (internal quotation mark omitted). "In applying the rational basis test, [courts] defer to the Legislature, which is presumed to know all the facts that would support a statute's constitutionality . . . . [A] statute is constitutional if rationally related to any conceivable legitimate State purpose." Smith v. West, 640 F. Supp. 2d 222, 241 (W.D.N.Y. 2009) (quoting People v. Walker, 81 N.Y.2d 661, 668 (1993)) (internal quotation marks omitted).

Here, section 181.21 easily satisfies rational basis review. Plaintiffs concede that "protecting children from transmission of disease is a compelling interest." Pls.' Motion 25-26. Additionally, "the interest of parents in the care, custody, and control of their children [] is perhaps the oldest of the fundamental liberty interests recognized by [the Supreme] Court." Troxel v. Granville, 530 U.S. 57, 65 (2000). Surely defendants have a legitimate interest in safeguarding this fundamental right of parents. The question, therefore, is whether the regulation is rationally related, under some reasonably conceivable set of facts, to the governmental interests in protecting children's health or safeguarding parents' ability to care for their children through informed decisionmaking.

The answer to this question must be "yes." With regard to protecting children's health, the record contains ample evidence that MBP puts infants at a serious risk of HSV-1 infection, which can result in brain injury or death. The letters and amicus submission from major national medical organizations, together with the testimony of numerous prominent experts in the field of infectious diseases, give us confidence that there is "overwhelming scientific evidence demonstrating the increased likelihood that newborns subject to direct oral suction will acquire HSV." Amicus Submission, at 4. Because of these expert submissions, and given that we need not find an "actual injury" under rational basis review but rather can rest our decision on any reasonably conceivable set of facts, we need not rely on the disputed MMWR Study to find that plaintiffs have failed to rebut the presumption that the regulation is constitutional.

Section 181.21 is also rationally related to the government's legitimate interest in safeguarding parents' ability to care for their children through informed decisionmaking. The required consent form, whether prepared by DOHMH or another party, will ensure that parents are aware when MBP will be performed on his child, informed about the risk of HSV-1 transmission from MBP, and empowered to decline consent for MBP prior to the circumcision. Indeed, not only does the written informed consent requirement further defendants'

interest in informed parental decisionmaking, but there appears to be no other equally effective mechanism for the government to ensure and verify that parents consent in advance to MBP.

Additionally, it is notable that, as plaintiffs concede, mohels' free exercise interest is not in performing MBP on babies without their parents' consent, but rather in performing MBP provided that the parents have consented. Tr. 42. In other words, mohels' free exercise interest is inherently circumscribed by parents' right to decide whether MBP is performed on their child or not. When mohels' free exercise interest is framed thusly, one can see how limited the regulation really is: it ensures that a prerequisite to a mohel's legitimate performance of MBP is in fact met. In light of these considerations, it is clear that the regulation is rationally related to the government's interest in fostering informed parental decisionmaking.

Based on the record before us, we conclude that section 181.21 satisfies rational basis review and is therefore constitutional. Plaintiffs are thus unlikely to succeed on the merits of their claim that the regulation violates their rights under the First Amendment's Free Exercise Clause.

2. Free Exercise Under Article I, Section 3 of the New York State Constitution

Article I, section 3 of the New York State Constitution provides:

> The free exercise and enjoyment of religious profession and worship, without discrimination or preference, shall forever be allowed in this state to all humankind; and no person shall be rendered incompetent to be a witness on account of his or her opinions on matters of religious belief; but the liberty of conscience hereby secured shall not be so construed as to excuse acts of licentiousness, or justify practices inconsistent with the peace or safety of this state.

N.Y. Const. art. I, § 3. In Catholic Charities of the Diocese of Albany v. Serio, 7 N.Y.3d 510 (2006), the Court of Appeals established the following balancing test for applying article I, section 3: "[W]hen the State imposes 'an incidental burden on the right to free exercise of religion' we must consider the interest advanced by the legislation that imposes the burden, and . . . '[t]he respective interests must be balanced to determine whether the incidental burdening is justified.'" Id. at 525 (quoting La Rocca v. Lane, 37 N.Y.2d 575, 583 (1975)). The Court of Appeals elaborated that "substantial deference is due the Legislature, and . . . the party claiming an exemption bears the burden of showing that the challenged legislation, as applied to that party, is an unreasonable interference with religious freedom." Id.

Here, section 181.21 satisfies the balancing test established in Serio. On one side of the balance, the regulation furthers two important governmental interests: safeguarding the health of children and protecting parents' ability to care for their children through informed decisionmaking. On the other side of the balance, the regulation imposes a relatively minor burden on the free exercise of religion: it does not ban MBP, does not compel mohels to communicate anything to parents, and does not regulate how MBP is performed; rather, it requires simply that mohels "obtain[]" a signed consent form prior to performing MBP.

In support of the regulation, several prominent experts in infectious diseases as well as four major national medical organizations have explained that MBP poses a serious risk to infants of HSV-1 infection, which could cause brain damage or death. By informing parents of this risk and advising that DOHMH does not consider MBP safe, the regulation will likely discourage some parents from consenting to MBP. Plaintiffs disagree, asserting that "it is very unlikely that [the] regulation will have any material impact on the practice of MBP in New York City" because Hasidic and Orthodox Jewish parents "believe[] themselves bound by a religious duty to include MBP as part of the ritual circumcision of their newborn baby boys, [thus] will not be dissuaded from fulfilling that duty by

countervailing 'advice' from a municipal agency." Pls.' Mot. 29. This argument is unconvincing. To start, the plaintiff organizations do not represent the parents and thus cannot speak for them. Tr. 42. Additionally, plaintiffs' argument rests on the unsupported assumption that, even after receiving information about risks to their newborns' health, Hasidic and Orthodox Jewish parents will uniformly dismiss such information. Although we do not know and do not opine on why parents might follow one religious practice or another, we do know that at least some Orthodox Jews do not believe that MBP is religiously mandatory. See Letter from David Zwiebel, Esq., Executive Vice President for Government and Public Affairs, Agudath Israel of America, to Thomas R. Frieden, MD, Commissioner, DOHMH (Mar. 4, 2005), at 1-2, Ex. L to Farley Decl. (estimating that although all of the boys enrolled in "Hasidic" schools would have had MBP performed, only half of the boys in "Non-Hasidic Hareidi" schools and "none of the boys" in "Modern Orthodox" schools would have had MBP performed). For parents who want their child to have a bris but do not want MBP performed, parents who support MBP but are unaware of its health risks and would consider these risks relevant, or parents who do not have a position on MBP because they do not know the practice exists, section 181.21 serves an important and legitimate function.

Looking to the regulation's history, it is notable that defendants did not enact the regulation immediately upon learning that MBP and neonatal herpes are linked, but rather pursued numerous educational outreach initiatives starting in 2005 before finally concluding in 2012 that educational outreach was insufficient to protect children. See Farley Decl. ¶¶ 69-87. The regulation that the Board of Health ultimately enacted, of course, does not prevent MBP nor regulate how it is performed, but merely requires informed parental consent in advance of the ritual. Especially given that the regulation is precisely within the expertise of the Board of Health, to which we at any rate owe "substantial deference," we find that plaintiffs have not shown that section 181.21 effects an "unreasonable interference with religious freedom." Serio, 7 N.Y.3d at 525. Plaintiffs are not likely to succeed on the merits of their claim that the regulation violates their right to free exercise of religion under article I, section 3 of the New York State Constitution.

D. The Public Interest

Under Second Circuit precedent, a party seeking a preliminary injunction must demonstrate not only irreparable harm and a likelihood of success on the merits, but also "that the public's interest weighs in favor of granting an injunction." Red Earth LLC v. United States, 657 F.3d 138,

143 (2d Cir. 2011) (quoting Metro. Taxicab Bd. of Trade v. City of New York, 615 F.3d 152, 156 (2d Cir. 2010)) (internal quotation mark omitted). Here, plaintiffs have failed to meet this burden. The testimony of defendants' experts and the letters from amici have established that MBP puts infants at a serious risk of HSV-1 infection. Further, the affidavit of Commissioner Farley has demonstrated that despite this risk, parents are sometimes unaware that MBP will be performed on their child until it occurs. Farley Decl. ¶ 94. MBP therefore implicates the governmental interests in safeguarding children's health and protecting parents' right to care for their children through informed decisionmaking, and section 181.21 directly furthers these interests by advising parents of the risks involved in MBP and requiring mohels to obtain parents' informed consent. Weighing these arguments in favor of the regulation against plaintiffs' arguments that the regulation violates the constitutionally enshrined principle of free exercise of religion, we conclude that plaintiffs have failed to show that the public's interest favors granting their motion for a preliminary injunction.

IV. Conclusion

This case implicates interests of the highest order. On the one hand, plaintiffs assert that section 181.21 burdens one of the foundational rituals of their Jewish faith. On the other

hand, defendants maintain that this ritual places infants at a serious risk of a potentially deadly infection and that parents might be unaware that their children are being exposed to this risk. The function of our law on free exercise of religion is to balance these conflicting interests and reach a principled resolution.

Under established Supreme Court precedent, a law burdening the exercise of religion is nonetheless presumed constitutional if it is neutral and generally applicable. What this means, in essence, is that the law must be neither underinclusive nor overinclusive: it must not regulate religious conduct while failing to regulate similarly harmful nonreligious conduct, and it must not regulate more religious conduct than is necessary to further the government's legitimate ends. Here, plaintiffs' vague and unsupported speculation about other types of regulation or education defendants could theoretically have pursued is insufficient to establish that the regulation is underinclusive. Further, because the regulation does not ban MBP nor regulate how MBP is performed, but merely requires informed parental consent, it is also plainly not overinclusive. Plaintiffs have not suggested any less restrictive regulation that defendants could have enacted that would have ensured that (1) parents were informed about the risks of MBP, and (2) parents had the ability to grant or deny consent in advance of

the circumcision. Accordingly, plaintiffs may defeat the regulation only by rebutting a strong presumption that the regulation is constitutional. Plaintiffs have failed to meet their burden: There is ample medical evidence that direct oral suction places infants at a serious risk of herpes infection, as well as evidence that parents are sometimes unaware in advance of a circumcision that MBP will occur, and the regulation plainly addresses these legitimate societal concerns. Additionally, the free exercise interest at stake -- mohels' interest in performing MBP uninhibited -- is inherently circumscribed because mohels have no right to perform MBP without parental consent. As enacted, the regulation does no more than ensure that parents can make an informed decision whether to grant or deny such consent.

Plaintiffs' additional argument that section 181.21 violates their free speech rights under the First Amendment is unconvincing because the regulation does not compel speech, and their argument that the regulation violates their free exercise rights under article I, section 3 of the New York State Constitution is unconvincing because the very limited restriction on plaintiffs' religious liberties is justified by the important governmental interests that the regulation furthers. Therefore, based on the record presently before us, we conclude that plaintiffs are not likely to succeed on the

merits of any of their claims. Additionally, in light of the quality of the evidence presented in support of the regulation, we conclude that a continued injunction against enforcement of the regulation would not serve the public interest.

For the reasons stated above, plaintiffs' motion for a preliminary injunction is denied. The stay of enforcement of section 181.21 is hereby terminated.

SO ORDERED.

Dated: New York, New York
January 10, 2013

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

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