

GIBSON DUNN

MEMO ENDORSED

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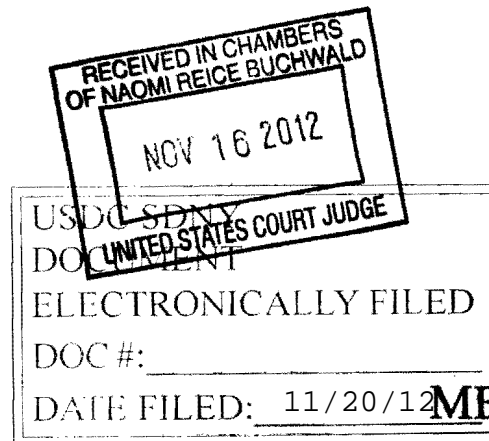
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November 16, 2012

VIA FACSIMILE

Hon. Naomi Reice Buchwald
Daniel Patrick Moynihan
United States Courthouse
500 Pearl St.
New York, NY 10007



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Re: *Central Rabbinical Congress of USA & Canada v. N.Y.C. Dep't of Health & Mental Hygiene*, No. 12-cv-7590 (S.D.N.Y.)

Dear Judge Buchwald:

I write on behalf of the American Academy of Pediatrics ("AAP"), the Infectious Diseases Society of America ("IDSA"), the Pediatric Infectious Diseases Society ("PIDS"), and the American Sexually Transmitted Diseases Association ("ASTDA") in opposition to the motion for a preliminary injunction filed by the plaintiffs in the above-captioned case. Our clients are the nation's foremost professional organizations of pediatrics, infectious diseases, pediatric infectious diseases, and sexually transmitted diseases physicians, and they are gravely concerned about the public health implications of an injunction against the implementation of the challenged parental consent regulation, and from a ruling that the regulation is unconstitutional. We respectfully request the Court's permission to file this *amicus* submission by letter in lieu of a formal motion.

We write regarding three central issues about which proposed *amici* have particular expertise, each of which has critical medical and public health implications. First, 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. Second, the regulation at issue is primarily directed at—and unquestionably furthers—the important public health and constitutional prerogative of ensuring informed parental decision-making, including communication of risks, before any non-emergency medical procedure is performed on a minor. Third, a ruling in plaintiffs' favor would severely hamper the government's ability to effectively address a wide range of public health concerns, as it would undermine officials' ability to rely on the advice and data-driven opinions of medical professionals in passing public health regulations.

Application
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Proposed *amici* respectfully submit that these medical and public health concerns should be considered by the Court in weighing the likelihood of success on the merits, balance of harms, and public interests at stake.¹ For these reasons and the reasons set forth more fully below, we respectfully request that the Court accept this letter in lieu of a formal *amicus* brief, and deny plaintiffs' motion for a preliminary injunction.

I. Infectious Diseases, Including HSV, Have Been Transmitted Through Direct Oral Suction, and Direct Oral Suction Increases the Risks Of Transmission

The clinical and epidemiological data evidencing the health risks of direct oral suction are incontrovertible. Numerous infectious diseases, including HSV, have been transmitted through direct oral suction, and direct oral suction increases the risk of infectious disease transmission.

The strong evidence that HSV can be, and has been, transmitted to a newborn when circumcision involves direct oral suction, and that newborns subject to direct oral suction after circumcision are at a greater risk of acquiring HSV, includes, but is not limited to, the epidemiologic investigations conducted by the New York City Department of Health and Mental Hygiene of eleven cases—including two deaths and at least two others who suffered brain damage—between 2004 and 2011. *See* Farley Decl., Ex. K; *see also* Goldberg-Cahn Decl., Ex. E (letters submitted to the City by PIDS and IDSA in support of the challenged regulation prior to its adoption).² For example, a 2004 study in *Pediatrics*, the professional journal of the AAP, reports on eight infants who acquired HSV shortly after they were subject to direct oral suction and concludes that the connection between direct oral suction following circumcision and genital HSV infection is strongly suggested by the following criteria: “exclusive genital distribution of the lesions, timing of their appearance (4-11 days after circumcision), isolation of HSV[], absence of HSV exposure in mothers (based on both clinical observation and negative [blood tests] in most of the mothers), and absence of clinical signs and symptoms consistent with HSV infections among family members.” Benjamin Gesundheit et al., *Neonatal Genital Herpes Simplex Virus Type 1 Infection After Jewish Ritual Circumcision: Modern Medicine and Religious Tradition*, 114 *Pediatrics* 259,

¹ *See Winter v. NRDC, Inc.*, 555 U.S. 7, 20, 24 (2008) (“A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest. . . . In each case, courts must balance the competing claims of injury . . . [and] courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.”) (quotation marks and citations omitted); *Pope v. County of Albany*, 687 F.3d 565, 570-71 (2d Cir. 2012) (applying *Winters* test in affirming denial of preliminary injunction); *G.B. v. Carrión*, 2012 U.S. App. LEXIS 12773, at *4 (2d Cir. June 22, 2012) (same).

² All citations to declarations and affidavits are to the declarations and affidavits submitted by the parties in support of and in opposition to the motion for a preliminary injunction in the instant case.

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259-60 (2004) (Farley Decl., Ex. J). Moreover, of the ritual circumcisers who agreed to be tested, all tested seropositive for disease. *Id.* at 260. The report further underscores not only the risk of transmission from ritual circumciser to baby, but also the severity of the HSV infection when acquired by an infant, as five of the eight infected infants in the study experienced severe complications as a result of HSV. One of those patients suffered “long-term brain damage manifested by seizures and infantile spasms,” and four of the infants “experienced recurrent episodes of genital herpes simplex” in addition to other medical complications. *Id.* These adverse events are consistent with the natural history of neonatal herpes.

Another recent report—this one published in the professional journal of PIDS by physicians in the Department of Pediatrics at Schneider Children’s Hospital of North Shore-Long Island Jewish Health System (now the Steven and Alexandra Cohen Children’s Medical Center of New York)—examined two infants who acquired HSV following Jewish ritual circumcision involving direct oral suction. The report concluded “that the mohel [ritual circumciser] who performed the circumcision was the source of the virus.” Lorry G. Rubin & Philip Lanzkowsky, *Cutaneous Neonatal Herpes Simplex Infection Associated with Ritual Circumcision*, 19 *The Pediatric Infectious Disease Journal* 266, 267 (2000) (Farley Decl., Ex. J). Significantly, both this article and the AAP study reiterate the prevailing view among infectious disease experts: that direct oral suction “has potentially important implications for transmission of infectious agents,” and that “public health officials and leaders of the Jewish community should act to modify the part of the circumcision ritual that involves direct oral contact with the blood and penis of” infants. *Id.*³ Not surprisingly, then, the AAP Task Force on Circumcision’s recently published Technical Report on Male Circumcision “advises against the practice of mouth-to-penis contact during circumcision, which is part of some religious practices, because it poses serious infectious risk to the child.” *Pediatrics* (August 27, 2012) (Farley Decl., Ex. Z) at e760.⁴

Two hundred years of historical data also supports the straightforward proposition that direct oral suction increases the risk of transmission of HSV and other infectious diseases. Indeed, as early as 1811, physicians had documented the risk of infectious agents passing from ritual circumciser to infant through the procedure. That year, Dr. Johann Rust, a prominent 19th

³ See also Gesundheit et al., *supra*, 114 *Pediatrics* at 260 (emphasizing that the act of direct oral suction “represents a potential source of orogenital transmission to the nonimmune whose skin integrity was disrupted by circumcision”).

⁴ The AAP Task Force on Male Circumcision is a “multidisciplinary workgroup” comprised of “AAP representatives from specialty areas as well as members of the AAP Board of Directors and liaisons representing the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the Centers for Disease Control and Prevention.” Technical Report at e756. The Task Force members “identified selected topics relevant to male circumcision and conducted a critical review of peer-reviewed literature by using the American Heart Association’s template for evidence evaluation.” *Id.*

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century medical expert, documented an outbreak of syphilis in Krakow among infants who had been subject to direct oral suction. Dr. Rust concluded that the “fatal epidemic” was due to the “venereal lesions . . . in the oral cavity of the local *mohel*.” Shlomo Sprecher, *Mezizah be-Peh—Therapeutic Touch or Hippocratic Vestige?*, Hakirah, the Flatbush Journal of Jewish Law and Thought Vol. 3 (2006), 15, 30-31 (Farley Decl., Ex. H). Similarly, in 1873 the New York City Board of Health investigated the cases of four otherwise healthy newborns who acquired genital ulcerations after they were subject to direct oral suction, three of whom ultimately died from their illnesses. *Id.* Subsequently, the *New York Medical Journal* published an article on those four cases which explained that the children most likely acquired their infectious diseases from the oral-genital contact between them and their circumcisers. See R. W. Taylor, *On the Question of the Transmission of Syphilitic Contagion in the Rite of Circumcision*, N.Y. Med. Journal 561, 561-82 (1873) (Farley Decl., Ex. I). Moreover, the historical record contains numerous other instances of infectious disease transmission through direct oral suction, including of tuberculosis to the penis and syphilis.⁵

Given 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, the risk associated with direct oral suction should be clearly communicated to parents or legal guardians in advance of the procedure, and written parental permission for the procedure should be obtained.⁶ The regulation at issue here accomplishes just that. The plaintiffs’ contention to the contrary is wrong and flies in the face of the modern understanding of infectious diseases transmission, as well as standard 21st century health care practices.

⁵ A comprehensive list of the documented outbreaks concerning the transmission of infectious diseases through direct oral suction can be found in Sprecher, *supra*, at 30-36 (Farley Decl., Ex. H). See also, e.g., E.L. Lewis, *Tuberculosis of the Penis: a Report of 5 New Cases, and a Complete Review of the Literature*, 56 J. Urol. 737-45 (1946) (Farley Decl., Ex. H) (reviewing 89 cases of primary tuberculosis of the penis, 72 of which occurred in infants after they were subject to direct oral suction).

⁶ Plaintiffs’ belief that they take “more than sufficient [precaution] to assure the safety of [the procedure]” simply by not performing direct oral suction when a ritual circumciser is experiencing “any cold sores,” Heber Aff. ¶ 8, is indicative of plaintiffs’ fundamental misunderstanding of the nature of HSV transmission through oral-genital contact. In fact, numerous studies have demonstrated that the transmission of HSV is possible even when an individual exhibits no oral lesions or is otherwise asymptomatic. For example, a 2008 study confirmed that “HSV shedding in the oral cavity is frequent and common in the absence of oral lesions and that oral secretions commonly contain infectious HSV.” Craig S. Miller & Robert J. Danaher, *Asymptomatic Shedding of Herpes Simplex Virus (HSV) in the Oral Cavity*, Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology, Vol. 105 No. 1 (Jan. 2008) at 43-44, 48 (Farley Decl., Ex. A); see also *id.* at 45 (listing twenty-two studies that found that a significant percentage of otherwise healthy individuals experience “asymptomatic shedding” of HSV from the oral cavity). Merely refraining from performing direct oral suction on a newborn when a ritual circumciser is experiencing cold sores is a dangerously insufficient preventive measure.

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II. Informed Parental Decision-Making, Including the Disclosure of Risks to the Parent, Serves A Vital Public Health Function and is a Constitutionally Protected Parental Right

Informed decision-making prior to the performance of invasive procedures serves a critical public health function, particularly when a procedure is performed on a minor. As a public health and public policy matter, then, parents—those ultimately responsible for their children’s well-being—must be able to make fully informed decisions regarding their children’s health. Risk disclosures are critical to such informed decision-making. These disclosures ensure that the patient or guardian is fully apprised of the risks before the procedure is performed, and that the patient or guardian is making the final decision with respect to the procedure in non-emergency situations. It is therefore commonplace for medical professionals to be required to disclose certain risks associated with a surgical or other medical procedure—including circumcision—and to require parents to give their written consent. *Cf. D.N.N. v. Berestka*, 2008 Minn. App. Unpub. LEXIS 136, at *6-7 (Minn. Ct. App. Feb. 5, 2008) (discussing the treating physician’s duty to obtain consent in the circumcision context).

The AAP set forth this principle in its policy statement on informed consent and parental permission, stating “that in most cases, physicians have an ethical (and legal) obligation to obtain parental permission” before undertaking “medical interventions.” *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, Pediatrics Vol. 95 No. 2 (Feb. 1995) at 317, available at <http://pediatrics.aappublications.org/content/95/2/314.full.pdf+html>. While circumcision is sometimes performed for cultural or religious reasons, it is nonetheless a surgical procedure; the decision as to whether and how to have it performed, as a matter of law and ethics, must necessarily involve the parent and include informed parental permission, in accordance with the principles set forth in the AAP policy statement. *See id.* at 134-17. Given the potentially severe consequences of the direct oral suction procedure, and in light of complaints from some parents that they did not know until after the fact that direct oral suction was going to be performed, it is clear that the challenged regulation is directed primarily at this fundamental medical-ethical principle of informed parental supervision of, and permission as to, the medical care decisions made on behalf of minors.

The Constitution and laws of the United States rightly reflect these public health and policy objectives. Parents’ interest “in the care, custody, and control of their children [] is perhaps the oldest of the fundamental liberty interests recognized by th[e] [Supreme] Court.” *Troxel v. Granville*, 530 U.S. 57, 65 (2000). Indeed, “it is cardinal with [the Court] that the custody, care and nurture of the child *reside first with the parents*.” *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (emphasis added). This is not only a parental right but also a “high duty,” *Pierce v. Society of Sisters*, 268 U.S. 510, 535 (1925), that applies in both religious

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and medical contexts. *See, e.g. Parham v. J.R.*, 442 U.S. 584, 602 (1979) (“Our jurisprudence historically has reflected Western civilization concepts of the family as a unit with broad parental authority over minor children. Our cases have consistently followed that course.”); *Wisconsin v. Yoder*, 406 U.S. 205, 233 (1972) (“The Court’s holding in *Pierce* stands as a charter of the rights of parents to direct the religious upbringing of their children.”).

Specifically, the Supreme Court has recognized that, “[s]urely, this [fundamental parental right] includes a ‘high duty’ to recognize symptoms of illness and to seek and follow medical advice.” *Parham*, 442 U.S. at 602. In fact, “[p]arents *must* make [the] judgments” that concern their children’s medical care and treatment. *Id.* at 603 (emphasis added). *See also, e.g., Pamela R. v. James N.*, 884 N.Y.S.2d 323, 330 (N.Y. Fam. Ct. 2009) (“[T]he custodial parent possesses the sole authority to make medical decisions for [his or] her child.”); *In re Martin F.*, 820 N.Y.S.2d 759, 772 (N.Y. Fam. Ct. 2006) (“Of course, a 3-year-old child by definition is incompetent to make his or her own medical decisions” and the parents have “a constitutional right (*i.e.* liberty interest) to the management of important medical decisions for th[eir] children.”). Indeed, parents have a personal constitutional right to be informed of and involved in the medical choices made on behalf of their children. *See Tenenbaum v. Williams*, 862 F. Supp. 962, 973 (E.D.N.Y. 1994). The challenged regulation protects this right.

The plaintiffs’ characterization of the City’s regulation as a form of compelled speech with respect to ritual circumcisers ignores the plain meaning and purpose of the consent requirement. The regulation does not require that the ritual circumciser provide any information; instead, it simply forbids any person from “perform[ing] 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.” The City Record, Sept. 21, 2012 (Goldberg-Cahn Decl., Ex. J) at 2600. The regulation requires parental knowledge of and consent to medical procedures performed on their children, and thus safeguards the parents’ right to raise their children as they see fit by ensuring that the parents are in a position to make an informed decision regarding their children’s religious practices and medical well-being. The required speech—such as it is—is that of the parent, not the ritual circumciser, as the required consent language makes clear: “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 [HSV] infection, which may result in brain damage or death.” *Id.* (emphasis added).

The purpose of this regulation, like informed consent laws generally, “is to allow the patient to evaluate [his or] her condition and render [his or] her best decision under difficult

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circumstances. Denying [the patient] up to date medical information is more of an abuse to [the patient's] ability to decide than providing the information.” *Texas Med. Providers v. Lakey*, 667 F.3d 570, 579 (5th Cir. 2012). This reinforces the well-established principle that “the doctor-patient relationship [exists] within the constraints of informed consent to the risks of medical procedures, as demanded by the common law, legislation and professional norms Speech incident to securing informed consent submits to the long history of this regulatory pattern.” *Id.* at 585 (Higginbotham, J. concurring). It is therefore not surprising that the government has broad authority to require that factual information be transmitted to the recipient of the medical procedure regarding potential risks.⁷ See, e.g., *Planned Parenthood v. Casey*, 505 U.S. 833, 882 (1992) (“recogniz[ing] a substantial government interest justifying a requirement that a woman be apprised of the health risks of abortion and childbirth”). The factual information must only be truthful, relevant and non-misleading. *Id.*

Rather than acting as a vehicle to unconstitutionally compel ritual circumcisers’ speech, as plaintiffs contend, the regulation merely forbids the performance of direct oral suction without written parental permission. This ensures that parents have been provided with truthful, relevant and non-misleading information regarding the documented risks of the procedure—whether by the City itself through its forms, or by the ritual circumciser, but only if he chooses to provide that information—and thereby protects the right of parents to make an informed decision regarding their infant’s medical care and religious upbringing, and to grant—or withhold—permission for the procedure.

III. Public Health and Policy Considerations Support Deference to Medical Professionals

The public health and policy considerations overwhelmingly support a government actor’s right to defer to the judgment of medical professionals when issuing public health regulations. State and local health boards must be permitted to defer to the professional medical judgment of their advisors when making such decisions, as government actors often have neither the resources nor the expertise to perform their own medical research or reach their own medical conclusions. Adherence to the dangerous standard proposed by the plaintiffs—namely, that *any* degree of disagreement within the medical community precludes reliance on prevailing scientific data and medical experts’ conclusions—would severely hamper the government’s ability to effectively address public health concerns.

Supreme Court precedent definitively establishes that “medical and scientific uncertainty” does not “foreclose the exercise of legislative power.” *Gonzales v. Carhart*, 550 U.S. 124, 164 (2007). In fact, to conclude that a procedure involves “risk” does not require that there

⁷ Given the children’s incompetency to consent and the parents’ fundamental right to make medical decisions on behalf of their children, the “recipient” in this case is, of course, the parent of the infant.

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be conclusive understanding of causation. Instead, standard protocol in the medical community is to recognize a strong correlation as a “risk” “while further studies are conducted to clarify whether various underlying factors play causal roles.” *Planned Parenthood v. Rounds*, 686 F.3d 889, 899 (8th Cir. 2012). “Thus, the truthful disclosure regarding increased risk cannot be unconstitutionally misleading or irrelevant simply because of some degree” of disagreement or uncertainty surrounding the underlying scientific facts. *Id.* at 900. Rather, the party challenging the existence of such risk must “show that any medical and scientific uncertainty has been resolved into a [scientifically accepted] certainty against a causal role.” *Id.*

This standard reflects the notion that “the [government], rather than a federal court, is in the best position to weigh [] divergent results and come to a conclusion about the best way to protect its populace.” *Id.* at 904. The City’s role in protecting the health and safety of the community is far too important to ignore scientific data showing a medical risk associated with direct oral suction. Ritual circumcisers’ religious freedom “does not include [the] liberty to expose the community or the child to communicable disease or the latter to ill health or death.” *Prince*, 321 U.S. at 166-67. It is, rather, for the City to rely on medical professionals’ risk assessment and to create public health policy and regulations accordingly. The challenged regulation does just that, and the Court should defer to that judgment.

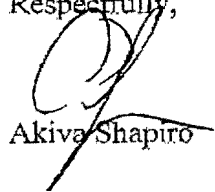
Here, New York City properly relied on the recommendations and conclusions of its medical advisors in deciding that direct oral suction poses health risks, a position supported by the medical community and overwhelming scientific evidence. The plaintiffs have failed to demonstrate that there is a scientifically accepted consensus against a causation between direct oral suction and HSV (and other infections) simply because no such consensus exists. Just the opposite—there is a clear consensus in the medical community that such risks are serious and real. Under the dangerous standard proposed by the plaintiffs, any dispute as to the medical facts justifying a public health regulation would render the regulation legally invalid. Not only would such a standard obviously undermine the government’s legitimate objective in preventing the communication of infection in the specific circumstances of direct oral suction, such a precedent would set the bar impossibly high for scientific certainty, thus undermining the entire basis for public health regulation.

For the foregoing reasons, the American Academy of Pediatrics, the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the American Sexually Transmitted Diseases Association respectfully request that this Court accept this letter in lieu of a formal *amicus* brief, and deny plaintiffs’ request for a preliminary injunction.

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Respectfully,



Akiva Shapiro

cc: All counsel of record (via facsimile)

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