

Abstract

The CDC is poised to recommend that physicians counsel the parents of every newborn boy and heterosexually active adolescent and man in the United States—approximately 36 million boys and men—that the benefits of circumcision outweigh the risks, that parents should take non-medical factors into account in making the "circumcision decision", and that Medicaid should pay for it.

The draft CDC recommendations are not medically correct, ethically sound, legally permissible, or procedurally valid. Accordingly, they should not be implemented and would be legally invalid if they are. They provide erroneous and misleading advice to physicians that exposes them to the threat of lawsuits by men and parents. The CDC must revise its draft guidelines to comport with the correct and prevailing view that circumcision is on balance deleterious to health; that men have the right to make the "circumcision decision" for themselves; that physicians are not permitted to circumcise healthy boys; and that Medicaid cannot be used to pay for unnecessary surgery.

The Draft CDC Circumcision Recommendations:
Medical, Ethical, Legal, and Procedural Concerns

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The Centers for Disease Control and Prevention ("CDC"), the nation's health protection agency, has issued the first ever draft federal circumcision recommendations¹ together with supporting background materials² for public comment. The CDC expects that its recommendations, if implemented, will increase the number of boys and men circumcised in the United States.³

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Draft CDC Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, STIs, and Other Health Outcomes ("Draft CDC Recommendations").
<<http://www.regulations.gov/#!docketDetail;D=CDC-2014-0012>>.

² Background, Methods, and Synthesis of Scientific Information Used to Inform the "Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, STIs, and other Health Outcomes" ("CDC Background Materials")
<<http://www.regulations.gov/#!documentDetail;D=CDC-2014-0012-0002>>.

³ CDC Background Materials, supra note 2, at 31-32.

Thousands of official comments have been filed opposed to the CDC proposal,⁴ however, and there have been public protests against it.⁵

This article asks the manifestly important question of whether the draft CDC circumcision recommendations are medically,⁶ ethically,⁷ legally,⁸ and procedurally justified.⁹ If not, what are the implications; can the draft recommendations be challenged; and what recommendations should the CDC be making about circumcision?¹⁰

THE DRAFT CDC RECOMMENDATIONS. According to the draft CDC recommendations, physicians should inform the parents of every newborn boy in the United States and all heterosexually active uncircumcised men as follows: (1) Circumcision has many medical benefits¹¹—including a reduced risk of urinary tract infections (UTIs), penile cancer, and sexually transmitted infections (STIs), especially a "dramatic" and "significant" 50% to 60% reduction in the risk of female-to-male transmission of HIV¹²—and these benefits outweigh the risks.¹³ (2) Parents have the right to make the "circumcision decision" for their sons, and in doing so should take into consideration, in addition to the health benefits and risks, religion, societal norms and customs, aesthetic preference, and hygiene.¹⁴ (3) The benefits of circumcision justify insurance paying for it, including the joint federal and state Medicaid insurance program.¹⁵

According to the draft CDC recommendations, neonatal circumcision has few disadvantages. Analgesia can substantially control pain.¹⁶ The complication rate is approximately 0.2%.¹⁷ The most common surgical complications, bleeding and infection, are usually minor and easily managed.¹⁸ Post-surgical complications are rare.¹⁹ Circumcision also leaves sexual function or satisfaction unchanged or improves it.²⁰

⁴ <<http://cdc.intactivist.net/?page=33&limit=100>> ("Public CDC Comments").

⁵ <<http://www.washingtontimes.com/news/2015/jan/15/circumcision-proposal-by-cdc-drawing-detractors/>>

⁶ See *infra* Part I at 2-9 .

⁷ See *infra* Part II at 9-10.

⁸ See *infra* Part III at 10-15.

⁹ See *infra* Part IV at 15-17.

¹⁰ See *infra* at 17-18.

¹¹ Draft CDC Recommendations, *supra* note 1, at 1; CDC Background Materials, *supra* note 2, at 7-22.

¹² Draft CDC Recommendations, *supra* note 1, at 2.

¹³ Draft CDC Recommendations, *supra* note 1, at 5; CDC Background Materials, *supra* note 2, at 38.

¹⁴ Draft CDC Recommendations, *supra* note 1, at 2; CDC Background Materials, *supra* note 2, at 5.

¹⁵ CDC Background Materials, *supra* note 2, at 38, 40.

¹⁶ Draft CDC Recommendations, *supra* note 1, at 5; CDC Background Materials, *supra* note 2, at 25.

¹⁷ CDC Background Materials, *supra* note 2, at 23.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at 26. Similarly, see 2012 American Academy of Pediatrics Task Force on Circumcision. Technical Report, Male Circumcision, *Pediatrics*, 130, no. 3 (2012): e756-e785 ("2012 AAP Technical Report") (Sexual Function and Penile Sexual Sensitivity).

THE BURDEN OF PROOF

As a group of 38 distinguished physicians from Europe and Canada wrote about circumcision in 2012:

It is commonly accepted that medical procedures always need to be justified because of their invasive nature and possible damaging effects.²¹ ... Preventive medical procedures need more and stricter justification than do therapeutic medical procedures, as they are aimed at people who are generally free of medical problems.²² ... Even stricter criteria apply for preventive medical procedures in children, who cannot weigh the evidence themselves and cannot legally consent to the procedure.²³

Thus, the burden is on the CDC to prove that circumcision generally—and its proposed guidelines in particular—are medically, ethically, and legally justified, and comply with the requirements for the issuance of highly influential medical recommendations, which these are.²⁴ This comports with the oft-stated legal rule that "he who avers must prove".²⁵ The benefit of the doubt must go to the boys and men who must live with the consequences of circumcision.

I. MEDICALLY JUSTIFIED?

Are the CDC's claims as to the medical pros and cons of circumcision accurate, and is circumcision medically justified?

A. Unscientific and Isolated Medical Opinion

1. *Undisclosed and Unaddressed Criticisms.* The CDC was an advisor the Academy of Pediatrics ("AAP"), which in 2012 issued a revised circumcision policy. The 38 physicians from Europe and Canada mentioned above published a comprehensive evidence-based critique of those recommendations.²⁶ The draft recommendations issued by the CDC in December 2014 are similar to the AAP's recommendations in 2012,²⁷ but the CDC failed in its duty to disclose the existence of that critique and others, which apply to its own recommendations, and to address the serious medical, ethical, and legal criticisms therein.²⁸ The CDC also has not responded as

²¹ M. Frisch et al., Cultural bias in the AAP's technical report and policy statement on male circumcision, *Pediatrics*, 131 (2013): 796-800 ("Cultural Bias"), at 797 (Criteria for Preventive Medicine).

²² *Id.*

²³ *Id.*; Hodges, F. M., Svoboda, J. S., & Van Howe, R. S. (2002), Prophylactic interventions on children: balancing human rights with public health, *Journal of Medical Ethics*, 28(1), 1-16.

²⁴ See *infra* Part IV at 15-17.

²⁵ See, e.g., He who avers must prove, Mills & Reeve LLP (U.K., August 22, 2013).

²⁶ Cultural Bias, *supra* note 21.

²⁷ Both policy statements contain the three principal recommendations cited above at notes 11-15.

²⁸ C. Kupferschmid et al., Commentary on the CDC "Recommendations for providers counseling male patients and parents regarding male circumcision and the prevention of HIV infection, STIs, and other health outcome (2015). <<http://www.regulations.gov/#!documentDetail;D=CDC-2014-0012-2455>> ("European CDC Critique").

required by law²⁹ to Van Howe's scathing peer review of its draft circumcision guidelines, or to the thousands of comments posted by the public, and by American physicians and 31 European physicians,³⁰ opposed to the CDC's draft recommendations.

2. *Lack of Scientific and Scholarly Rigor.* The draft CDC recommendations show an obvious lack of scientific and scholarly rigor. For example, the CDC draft contains only 255 references, some of which are redundant, while a Pub Med search for "circumcision" identified 6,338 publications.³¹

3. *The Opposite of the Prevailing Medical Opinion Worldwide.* The draft CDC recommendations are the opposite of the prevailing view among physicians and medical associations in the Western world that there is no valid medical basis for circumcision, that it is unethical for physicians to circumcise healthy boys, and that circumcision violates the rights of the child.³² "Remarkably, the draft fails to mention all the medical organizations outside of the United States who have weighed in with an opposing opinion on male circumcision."³³ "Furthermore, the CDC does not discuss that the U.S. is an outlier with respect to circumcision policy and rates compared to other OECD countries"³⁴

4. *Scientifically Untenable.* The German pediatric association concluded that the similar 2012 circumcision recommendations by The American Academy of Pediatrics "has been graded by almost all other paediatric societies and associations worldwide as being scientifically untenable".³⁵ The same comment applies to the draft CDC recommendations.

B. Undisclosed and Understated Disadvantages

"The CDC made no serious attempt to review the pain, risks, complications, or harms associated with circumcision."³⁶

1. *Understated Risks and Unknown Complication Rate.* The CDC makes the false claim in its recommendations that circumcision is safe, while admitting in its background materials and thus knowing the opposite, that it risks a long list of minor injuries, serious injuries, and occasionally death. The CDC claims a complication rate of 0.2%, but this is deceptive as the CDC is only referring to risks during the surgery. The CDC states that the median complication rate during

²⁹ See *infra* Part IV at 15-17.

³⁰ European CDC Critique, *supra* note 28.

³¹ R.S. Van Howe, A CDC-requested, Evidence-based Critique of the Centers for Disease Control and Prevention 2014 Draft on Male Circumcision: How Ideology and Selective Science Lead to Superficial, Culturally-biased Recommendations by the CDC (2015), at 1 ("Van Howe Peer Review").

³² Cultural Bias, *supra* note 21, and European CDC Critique, *supra* note 28.

³³ Van Howe Peer Review, *supra* note 31.

³⁴ Van Howe Peer Review, *supra* note 31.

³⁵ <http://www.intactamerica.org/german_pediatrics_statement> (translated) ("German Critique").

³⁶ Van Howe Peer Review, *supra* note 31.

and after the surgery is 1.5%; European physicians put the complication rate at 2%; others call 2% to 10% a reasonable estimate; but severe meatal stenosis was found in 20% of boys 5-10 years after circumcision in the neonatal period,³⁷ often requiring surgical correction. The CDC did not disclose this.³⁸ In a 1999 survey, men aggrieved to have been circumcised reported much higher complication rates than these.³⁹ As the AAP admitted in 2012, "[t]he true incidence of complications after newborn circumcision is unknown".⁴⁰ Likewise, the CDC states, "Because of their rarity, rates of severe complications are difficult to document",⁴¹ which concedes that *the CDC does not know the true incidence of minor complications, severe complications, and fatalities caused by circumcision*. "The medical community has never studied (retrospectively or prospectively) the long-term outcomes to men from infant circumcision".⁴² Attorneys for the Rights of the Child notes a long list of judgments and settlements for circumcision injuries, which likely represent the tip of the iceberg.⁴³ As Garber commented, "It is inconceivable that the AAP [and now the CDC] could have objectively concluded that the benefits of the procedure outweigh the risks when the 'true incidence of complications' isn't known."⁴⁴ Without knowing the risks associated with circumcision, It is improper for the CDC to recommend that physicians discuss circumcision with parents and heterosexually active adolescents and men, which is to say offer it to them, and tell them that the complication rate is .2%, when the risks associated with circumcision are many times higher, and their true extent is unknown. This will mislead the parents and men; their consent to circumcision will not be fully informed; and the millions of boys and men who will be circumcised as a result will be exposed to a much higher risk of complications than the CDC claims.

2. *Pain Understated*. The CDC states, "appropriate analgesia can substantially control pain",⁴⁵ implying that infants being circumcised experience little pain. First, the CDC's statement concedes that circumcision is painful, and that appropriate analgesia does not eliminate pain. Second, the statement falsely implies that physicians use appropriate analgesia during

³⁷ Joudi, M. et al.: Incidence of asymptomatic meatal stenosis in children following neonatal circumcision. *J Pediatr Urol* 7(5): 526-528 (2011).

³⁸ Van Howe RS: Incidence of meatal stenosis following neonatal circumcision in a primary care setting. *Clin Pediatr* 2006; 45(1): 49-54.

³⁹ The National Organization to Halt the Abuse and Routine Mutilation of Males (NOHARMM) sent a survey to individuals who had had previously contacted organizations opposed to circumcision. T. Hammond, Preliminary Poll of Men Circumcised in Infancy or Childhood, *BJU International* 83, Supp. 1, 85-92 (1999), at 58-92 ("1999 Hammond Poll"). <<http://www.noharrrm.org/bju.htm>>.

⁴⁰ 2012 AAP Technical Report, supra note 20, at e772 (emphasis added).

⁴¹ CDC Background Materials, supra note 2, at 25.

⁴² Unpublished 2012 Hammond Poll, available from the author.

⁴³ See <<http://arclaw.org/resources/settlements>>.

⁴⁴ S.T. Garber, *The Circular Cut: Problematizing the Longevity of Civilization's Most Aggressively Defended Amputation*, Wesleyan University Thesis (2013), at 69.

⁴⁵ CDC Background Materials, supra note 2, at 25.

circumcision surgery, when often no anesthetics are used.⁴⁶ Third, Cold and Taylor suggest that anesthetics are largely ineffective.⁴⁷ The CDC itself reports that in a South African trial, 31.7% of African *men* reported pain.⁴⁸ Moreover, pain is subjective. Taddio et al. found that circumcised infants show a stronger pain response to subsequent vaccination and that "pain experienced by infants in the neonatal period may have long-lasting effects on future infant behavior".⁴⁹ Recently, an article reports a double risk of infantile autism before the age of 5 years in circumcised boys.⁵⁰ Thus, circumcision pain in infancy may change how the brain functions, but the CDC does not advise physicians to inform parents of this alarming possibility.

3. *No Discussion of the Foreskin.* The CDC has given physicians and thereby parents and men no information about the anatomy, histology, physiology, and function of the body part being removed, the male foreskin. Without such information, parental consent will not be fully informed as the law requires. Imagine the CDC recommending that physicians discuss with parents amputating other body parts from boys or girls without thoroughly analyzing the body part being removed, addressing all medical, ethical, and legal criticisms, and without justifying the removal of the body part beyond all reasonable doubt.

4. *Omission that Circumcision May and In Fact Does Impair Men's Sex Lives.* The CDC recommendations do not mention anything about whether circumcision affects men's sex lives.⁵¹ The CDC's background materials also do not mention that the foreskin is erogenous. They devote only one paragraph to sexuality, citing a survey finding that "[a]dult men who undergo circumcision generally report minimal or no change in sexual satisfaction" or an improvement.⁵² This implies that men and their parents need not be concerned that circumcision does or might affect men's sex lives.

The CDC then contradicts itself by citing in its background materials a survey that found "decreased erectile function and penile sensation", by acknowledging that the foreskin is "highly innervated",⁵³ and by expressly acknowledging that *circumcision risks "the possibility of adverse*

⁴⁶ Council on Scientific Affairs. Report 10: Neonatal circumcision. Chicago: American Medical Association, 1999.

⁴⁷ Cold CJ, Taylor JR. The prepuce. *BJU Int* 1999;83 Suppl. 1:34-44, at 34 ("Cold and Taylor") (Innervation of the Prepuce).

⁴⁸ CDC Background Materials, *supra* note 2, at 25-26.

⁴⁹ Taddio A, Katz J, Ilersich AL, Koren G. Effect of neonatal circumcision on pain response during subsequent routine vaccination. *Lancet*. 1997;349(9052):599-603 ("Circumcised infants showed a stronger pain response to subsequent routine vaccination than uncircumcised infants").

⁵⁰ M. Frisch and J. Simonsen, Ritual circumcision and risk of autism spectrum disorder in 0- to 9-year-old boys: national cohort study in Denmark, *J R Soc Med* (January 8, 2015). <<http://jrs.sagepub.com/content/early/2015/01/07/0141076814565942.abstract>>.

⁵¹ Draft CDC Recommendations, *supra* note 1.

⁵² Draft CDC Recommendations, *supra* note 1, at 7.

⁵³ CDC Background Materials, *supra* note 2, at 26.

effects on sexual sensation and function".⁵⁴ Thus, the CDC is recommendation that parents be told nothing about whether circumcision might adversely affect men's sex lives, even though the CDC concedes the opposite, that it may. If parents were informed that circumcision might impair their son's sex lives, they might not consent to it. In those cases, the parental consent will not be fully informed and will be legally invalid, exposing physicians to lawsuits.

In fact, the CDC's acknowledgment in background materials that circumcision *may* adversely affect men's sex lives is false and misleading as well, because circumcision *does* adversely affect men's sex lives. It plainly destroys how the normal penis functions. Once the foreskin is removed, it is no longer able to move to and fro over the glans penis and down toward the base of the penis in the so-called "gliding action". The prevailing opinion worldwide is that circumcision also impairs sexual sensation and satisfaction. An oft-cited 2007 study suggests that circumcision desensitizes and removes the most sensitive part of the penis.⁵⁵ Bossio et al. stated in a 2014 review, "Adverse self-reported outcomes associated with foreskin removal in adulthood include impaired erectile functioning, orgasm difficulties, decreased masturbatory functioning (loss in pleasure and increase in difficulty), an increase in penile pain, a loss of penile sensitivity with age, and lower subjective ratings of penile sensitivity".⁵⁶

Thus, circumcision *does* impair men's sex lives, and the CDC should have disclosed that fact in its recommendations. Let us assume that all the CDC knows is that circumcision *might* impair men's sex lives, as the CDC concedes in its background materials. First, the CDC should have disclosed that risk in its recommendations. The public, the press, and physicians are likely to read only the recommendations—or more likely the press release about the recommendations—and not the background materials. Second, applying the precautionary principle of medicine, the benefit of the doubt as to whether circumcision impairs the sex lives of adolescent boys and men must be given to boys and men. The CDC should not be recommending discussing circumcision with anyone, which it states will increase the circumcision rate, when the CDC admits that circumcision may adversely affects men's sex lives, and when circumcision does in fact impair men's sex lives.

⁵⁴ Id. at 4.

⁵⁵ M.L. Sorrells, J.L. Snyder, M.D. Reiss et al., Fine-Touch Pressure Thresholds in the Adult Penis, *BJU International*, 99 (2007): 864-869, 864. See also Cultural Bias, *supra* note 21, at 798 ("Recent studies, several of which were not included in the AAP report ... suggest that circumcision desensitizes the penis and may lead to sexual problems in circumcised men and their partners").

⁵⁶ Bossio, J. A., Pukall, C. F., & Steele, S. (2014). A review of the current state of the male circumcision literature. *The Journal of Sexual Medicine*, 11(12), 2847–2864, at 2853, cited in B. Earp, Do the benefits of male circumcision outweigh the risks? A critique of the proposed CDC guidelines. *Front. Pediatr.* 3:18 (2015) ("Earp CDC Critique"), at 3.

5. *Penile Reduction Surgery.* The CDC has not disclosed to men or the parents of newborns that circumcision surgery reduces the width of the penis and decreases its length on average by 3/10" in the adult male.⁵⁷

6. *Undisclosed Risk of Anger and other Psychological Harm.* The CDC has ignored the literature about the potential deleterious psychological effects of circumcision, including the increasing probability of regret of anger at one's parents. The word "psychological" does not appear in the draft CDC recommendation or in the background paper. "It is hard to believe, that the CDC is unaware of the literature concerning this subject."⁵⁸ Adverse psychological effects after circumcision have been observed in infants.⁵⁹ Physicians who follow the CDC's recommendations, if implemented, will not be fully informing adolescents, men, and parents about the risk of resentment, anger, and psychological harm,⁶⁰ as the law requires, again exposing physicians to lawsuits by the men and parents.

7. *Undisclosed Certainty of Harm.* The CDC does not acknowledge the obvious, that circumcision harms all boys and men. As a California Appeals Court stated in 2006,

[I]t seems self-evident that unnecessary surgery is injurious and causes harm to a patient. Even if a surgery is executed flawlessly, if the surgery were unnecessary, the surgery in and of itself constitutes harm ... the patient needlessly has gone under the knife and has been subject to pain and suffering".⁶¹

Circumcision also radically changes the appearance of the normal penis, destroys its mobility, and leaves a scar, evidence of a wound.⁶² A German court similarly ruled in 2012 that circumcision inflicts "bodily harm".⁶³ Thus, circumcision harms all boys and men, whether they recognize it or not.

C. Exaggerated Benefits

⁵⁷ "There was a significant difference in length, with the uncircumcised men having a mean length 8 mm greater than the circumcised". J. Richters et al., Are Condoms the Right Size(s)? A Method for Self-Measurement of the Erect Penis, *Venereology* Vol. 8 No. 2, May 1995, at 80.

⁵⁸ European CDC Critique, supra note 28.

⁵⁹ Taddio A, Katz J, Ilersich AL, Koren G. Effect of neonatal circumcision on pain response during subsequent routine vaccination. *Lancet.* 1997;349(9052):599–603 ("Circumcised infants showed a stronger pain response to subsequent routine vaccination than uncircumcised infants").

⁶⁰ See, e.g., Boyle GJ, Goldman R, Svoboda JS, Fernandez E. Male circumcision: Pain, trauma and psychosexual sequelae. *J Health Psychol* 2002; 7: 329-343.

⁶¹ *Tortorella v. Castro*, 140 Cal.App.4th 1, 43 Cal.Rptr.3d 853, Cal.App. 2 Dist. (2006).

⁶² Cold and Taylor, supra note 47, at 96 ("Histology of the male circumcision scar shows amputation neuromas, Schwann cell proliferation and the bulbous collection of variably sized neurites. Amputation neuromas do not mediate normal sensation and are notorious for generating pain.")

⁶³ German court rules circumcision is 'bodily harm', BBC News June 26, 2012, at <<http://www.bbc.com/news/world-europe-18604664>>.

1. *Misleading Discussion of "Benefits"*. Circumcision does not have the benefits that the CDC claims for it. The CDC's principal claim that "the benefits outweigh the risks" is false. First, this implies that all boys and men will benefit from the surgery when, at best, circumcision has only *potential benefits*. The CDC claims that circumcision reduces female-to-male transmission of HIV by an impressive sounding 50% to 60%, but this will mislead parents and men as this is the *relative risk reduction*; the *absolute risk reduction* is only an unimpressive sounding 1.3%. The CDC further misleads decision makers by stating the potential reduction in HIV risk in relative terms (50% to 60%) while stating the risks of circumcision in absolute terms. This inflates the potential benefits of circumcision in relation to the related risks and harms.

2. *No Meaningful Benefit During Childhood*. The only potential benefit that the CDC and the AAP claim for boys during childhood is a 1% reduction in UTI's, but UTI's can be treated with antibiotics.⁶⁴ The other claimed small speculative potential future benefits—a slight reduction in penile cancer and some STI's—occur in adulthood. Boys are not at risk of penile cancer or STI's. The CDC "does not discuss the necessity of circumcision in male newborns and infants for the later prevention of STD. Why the rush? Infants are not coitally active"⁶⁵

3. *Unproven that Circumcision Reduces HIV in Africa and the U.S.* The CDC's principal claim that circumcision has significant efficacy in dramatically reducing HIV in the United States is knowing false. First, the CDC,

... assumes that the randomized clinical trials in Africa could not harbor any bias (the CDC draft actually states this) and did not question the methodology of these studies, although their methodology has been questioned extensively ... Any evidence that does not support the CDC's presumption is either ignored, criticized, or dismissed. As a consequence, the draft is laughably biased.⁶⁶

Thus, it is unproven whether circumcision reduces HIV in heterosexually active men by 1.3% even in Africa. Second, let us grant for purposes of argument that it does. The CDC simply assumes that circumcision will reduce HIV by the same 1.3% in the United States. There is no evidence that experiments in Africa can be applied to newborn boys, infants, and heterosexually active adolescents and men living in the United States or in other countries with much lower HIV prevalence than found in the African trial sites. The CDC admits this, as in its background materials, the CDC only states that circumcision is *likely* to reduce HIV in the U.S., not that it *does*. Thus, the CDC has contradicted itself again, claiming a dramatic and significant reduction in HIV in the U.S. while conceding that it may not reduce HIV in the U.S. at all. The CDC's materials also contains no discussion of the observation that HIV rates are and have remained

⁶⁴ Cultural Bias, supra note 21.

⁶⁵ European CDC Critique, supra note 28.

⁶⁶ Van Howe Peer Review, supra note 31.

low in Europe, Canada, Australia and New Zealand, despite much lower circumcision rates in those countries than in the U.S. These countries also do not have higher rates of other STI's or UTI's in childhood in comparison than the U.S.⁶⁷

According to the CDC, there have been fewer than 50,000 new cases of HIV annually in the U.S. since the mid-1990's,⁶⁸ and in 2011, only 10% of these arose from female-to male transmission of HIV.⁶⁹ As Bundick states, since 70% to 80% of American men are circumcised, "*the data suggest that the number of HIV infections that could be prevented in the US by promoting infant male circumcision is likely to be only in the hundreds per year*".⁷⁰

Moreover, as the CDC impliedly concedes in its background materials,⁷¹ men can acquire HIV from women during circumcision wound healing.⁷² In addition, according to the CDC, 17% of circumcised men mistakenly believe that if they are circumcised, they do not need to practice safe sex.⁷³ Not disclosed by the CDC, circumcised men engage more frequently in anal sex,⁷⁴ which the federal government states is the highest high risk factor for HIV infection.⁷⁵ Thus, even if circumcision would otherwise reduce HIV by 1.3% in Africa, which is unproven, and even if it reduced HIV by the same percentage in the U.S., for which there is no evidence, after taking into consideration these risk factors and lower condom use by circumcised men, circumcision may cause a net *increase* in HIV among men in the U.S. The CDC also has not disclosed that male circumcision will increase HIV among female sexual partners in the U.S. due to transmission during wound healing.

4. *No Number-Needed-to-Treat or Number-Needed-to-Harm.* The draft CDC recommendations contain no information about numbers-needed-to-treat (NNT) or the number-needed-to-harm (NNH), which are critical for decision-makers to know. It would be necessary to circumcise approximately 100 newborn boys to prevent 1 urinary tract infection during infancy at a cost of 2 complications, according to European physicians. Considering that UTIs can be and almost always are treated by antibiotics, the number needed to harm by circumcision to benefit a single boy is actually much higher than 100 to 1. Insofar as circumcision harms all boys and men, the disadvantages of circumcision outweigh the potential benefits in childhood by 100 to 1 or more.

⁶⁷ European CDC Critique, supra note 28.

⁶⁸ CDC Background Materials, supra note 2, at 11.

⁶⁹ CDC Background Materials, supra note 2, at 27.

⁷⁰ S. Bundick, Promoting infant male circumcision to reduce transmission of HIV: A flawed policy for the US, Health and Human Rights Journal (August 31, 2009) ("Bundick Critique").

⁷¹ CDC Background Materials, supra note 2, at 12.

⁷² Johns Hopkins Medicine, News and Publications, As Circumcision Wounds Heal, HIV-Positive Men May Spread Virus To Female Partners, Study Shows (April 28, 2015).

⁷³ CDC Background Materials, supra note 2, at 30.

⁷⁴ Cold and Taylor, supra note 47 (Sexual Function).

⁷⁵ AIDS.gov, Lower Your Sexual Risk of HIV ("Anal sex is the highest-risk sexual activity for HIV transmission").

Thus, the CDC's implied claim that the benefit of circumcision outweigh the disadvantages, which parents and men will rely upon, is false.

To prevent one case of penile cancer, it would be necessary to circumcise between 909 and 322,000 boys, causing 18 to 644 complications according to European physicians, and harming all 909 to 322,000 boys and men.⁷⁶ Penile cancer is a rare disease that usually occurs in old age; it can be treated in early stages; and even in later stages the treatment might be circumcision.

As stated, according to the CDC's own numbers, circumcising 80 million American men would prevent HIV in only hundreds of men per year. All 80 million of those men would be harmed through loss of their foreskin, and 2% or 1.6 million of them would suffer complications according to European physicians (or more since the number of complications is unknown and likely higher).

D. Any Potential Benefits Can Be Achieved More Effectively Without Circumcision

Moreover, since urinary tract infections in infants can be treated with antibiotics, there is no reason to circumcise any boy to prevent a UTI, let alone 100 or more boys to prevent one UTI at the risk of 2 or more complications. The risk of penile cancer—as rare as the risk of being struck by lightning—can be further reduced to close to zero by washing one's penis with soap, something that boys and men in the United States are likely to do without needing encouragement. The CDC has presented no information about non-invasive prophylactic measures for preventing HIV and STI's, namely abstinence, monogamy, HPV immunization, and the use of condoms, heavily promoted by the United States government a few years after HIV was discovered. Condoms are almost 100% effective, and so long as men engaging in dangerous sex use condoms, which they must continue to do or risk infection, circumcision adds no benefit. It is inexcusable that the CDC promotes circumcision to reduce HIV and does not even mention condoms, which men must use during dangerous sex or risk HIV infection, AIDS, and possibly death.

II. UNBIASED AND ETHICALLY JUSTIFIED?

A. Biased

The CDC was a consultant to the AAP when the AAP prepared its 2012 circumcision policy statement. The charitable organization Doctors Opposing Circumcision has accused the AAP's 2012 circumcision recommendations, which are similar to the CDC's recommendations, as being

⁷⁶ Learman, L.A.: Neonatal circumcision: a dispassionate analysis. *Clin Obstet Gynecol.*1999;42(4):849–859; Christakis, D. A., Harvey, E., Zerr, D. M., Feudtner, C., Wright, J. A., Connell, F. A.: A trade-off analysis of routine newborn circumcision. *Pediatrics.* 2000;105(1 pt 3):246–249.

financially, religiously, and culturally biased.⁷⁷ Van Howe, a peer reviewer, states, "The list of participants [at the CDC in 2007] reads like a Who's Who of Circumcision Advocates. No group opposing circumcision was allowed any input." This violates the requirement by the federal government that important medical guidelines such as these be unbiased, evidence based, and free from any conflicts of interest.⁷⁸ Van Howe calls the CDC guidelines "laughably biased" medically as well,⁷⁹ and deaf to criticism that circumcision does not prevent HIV in the U.S.⁸⁰ The CDC did not disclose possible or actual biases and conflicts of interest in its draft recommendations or background materials, as is required and is the norm.⁸¹ Circumcision decision makers will not be fully informed as the law requires unless physicians disclose their biases.

B. No Serious Ethical Discussion

The CDC documents, like the 2012 circumcision recommendations of The American Academy of Pediatrics, do not contain any serious discussion of the central ethical and legal dilemma as to who has the right to make the circumcision decision, parents or their sons, the boys being operated upon, when they reach the age of legal consent.

C. Unnecessary Surgery is Unethical

The AMA Code of Medical Ethics states, "Under no circumstances may physicians place their own financial interests above the welfare of their patients. ... *For a physician to unnecessarily hospitalize a patient ... for the physician's financial benefit is unethical.*"⁸² Recommending or performing unnecessary surgery is also inconsistent with ethical practice, because all surgical procedures bear some degree of risk. "*Performing unnecessary surgery is a major betrayal of the surgeon's paramount obligation to place the patient's best interests first.*"⁸³

D. Circumcision Violates Many Other Ethical Rules

Circumcision breaches numerous ethical rules: (1) the *fiduciary duty* of physicians only to perform medical procedures on a child that the child would consent to if able to make the decision for himself; (2) the "*best interests*" rule, which the CDC acknowledges, whereby physicians must act in a patient's best interest; (3) the *autonomy* of the patient—a rule that the

⁷⁷ Doctors Opposing Circumcision, Commentary on American Academy of Pediatrics 2012 Circumcision Policy Statement. <http://www.doctorsopposingcircumcision.org/pdf/2013-04-24_Commentary.pdf> ("DOC Critique".)

⁷⁸ See *infra* Part IV at 15-17.

⁷⁹ Van Howe Peer Review, *supra* note 31.

⁸⁰ *Id.*

⁸¹ See *infra* notes 142-143.

⁸² AMA Code of Medical Ethics - Opinion 8.03 - Conflicts of Interest: Guidelines.

⁸³ American Academy of Ophthalmology, Advisory Opinion of the Code of Ethics, Unnecessary Surgery and Related Procedures (2008). <<http://www.aao.org/about/ethics/upload/Unnecessary-Surgery-2008.pdf>>.

CDC acknowledges but ignores⁸⁴—whereby medical decisions for children that are not essential to their wellbeing and that can be deferred, such as elective surgery, must be deferred;⁸⁵ (4) the cardinal rule of *non-maleficence*, or the Hippocratic Oath to "First, Do No Harm";⁸⁶ (5) *beneficence*, whereby "all surgical or other interventions must ... have some reasonable prospect of providing a tangible benefit to him [each individual boy];"⁸⁷ (6) the rule of *proportionality*, whereby, "[i]f other less risky but equally beneficial treatment options are available [as here], they should be considered instead of surgery";⁸⁸ and (7) the rule of *justice*.⁸⁹ It is unjust to circumcise boys when genitally intact men rarely choose it for themselves, when increasing numbers of men are angry to have been circumcised without their consent, when physicians do not cut the genitals of healthy girls, or surgically remove other body parts from healthy children. These ethical rules all prohibit physicians from circumcising healthy boys.

III. LEGALLY JUSTIFIED?

A. Unlawful to Charge Medicaid for Circumcision

It would be unlawful for physicians to follow the CDC's recommendation number (3) above,⁹⁰ that physicians are justified in charging Medicaid to circumcise boys whose parents are unable to pay for the surgery. The fundamental rule of Medicaid law, contained in the federal and all state Medicaid statutes and regulations,⁹¹ and confirmed by the U.S. Supreme Court,⁹² is that Medicaid only covers services that are "medically necessary".⁹³ As the Canadian Paediatric Society states, "circumcision is a 'non-therapeutic' procedure, which means it is not medically necessary".⁹⁴ Likewise, the CDC does not recommend circumcision, and calls it elective surgery,⁹⁵ meaning that parents can consent to it or not as they please.⁹⁶ It is obvious that circumcision is not

⁸⁴ CDC backgrounds materials, supra note 2, at 39-40 ("The PHEC subcommittee concluded that the disadvantages associated with delaying male circumcision would be ethically compensated to some extent by the respect for the integrity and autonomy of the individual.)

⁸⁵ See generally Cultural Bias, supra note 21.

⁸⁶ Diekema Affidavit, Plaintiff's Reply Memorandum of Law, Superior Court of Washington in and for Jefferson County (January 18, 2006) (emphasis added) ("Diekema Affidavit") (available from the author).

⁸⁷ Diekema Affidavit, supra note 86.

⁸⁸ Diekema Affidavit, supra note 86.

⁸⁹ See, e.g., Diekema et al., *Clinical Ethics in Pediatrics, A Case-Based Textbook* (2011).

⁹⁰ Supra note 15.

⁹¹ See infra Part IV at 15-17.

⁹² *Schweiker v Hogan*, 457 US 569 at 573 (1982), citing 42 USC 42 USC § 1396a(a)(10)(C); *Beal v Doe*, 432 US 438 (1977).

⁹³ See, e.g., 42 USC Sec. 1396 et seq. (practitioners must furnish only medically necessary care); and 42 CFR Sec. 561.1; CHMS Manual, Sec. 142 (8) ("All services provided must be based on medical necessity"). Under federal law, all state Medicaid statutes must contain this provision.

⁹⁴ Canadian Paediatric Society, *Circumcision: Information for Parents* (November 2004).

⁹⁵ See, e.g., Draft CDC Recommendations, supra note 1, at 1; CDC Background Materials, supra note 2, at 39.

⁹⁶ See, e.g., Draft CDC Recommendations, supra note 1, at 1 (concerning counseling parents about decision making).

medically necessary: most men who have ever lived have been genitally intact, as are approximately 70% of men now living.⁹⁷ Even if circumcision had all of the medical benefits that the CDC, The American Academy of Pediatrics, and other proponents of circumcision claim for it, and no risks or other disadvantages, insofar as it is not medically necessary, under federal and state law, it is not a covered Medicaid benefit under any circumstances.⁹⁸ Physicians who charge Medicaid for circumcision as the CDC recommends commit Medicaid fraud, violate federal and state False Claims Acts, and risk large penalties and multiple damages for every circumcision that they perform.⁹⁹

B. Unlawful to Allow Circumcision for Reasons Having Nothing to do With Medicine

The CDC's second argument above is that in making the "circumcision decision", parents should take into account, in addition to health benefits and risks, "religion, societal norms and social customs, hygiene, aesthetic preference, and ethical considerations".¹⁰⁰ This argument fails as well, for several reasons. First, as discussed above, ethical considerations prohibit non-therapeutic circumcision. Second, the U.S. Supreme Court has settled that parents cannot risk harming or harm their children, as circumcision does, for religious reasons,¹⁰¹ nor could the rule that the safety of children is of paramount importance be changed.¹⁰² Third, pursuant to various federal laws, regulations, and executive orders discussed below, the CDC must ensure that its recommendations are *scientifically objective* and *justified by medical evidence*.¹⁰³ In taking non-medical factors into consideration, the CDC violates its pledge to "[b]ase all public health decisions on the highest quality *scientific data* that is derived openly and *objectively*" by "[p]utting science into action" to find "*the most effective ways to prevent [disease]*."¹⁰⁴ The CDC's mandate and pledge prohibit it from recommending that parents make decisions about circumcision for reasons having nothing to do with medicine. Fourth, the draft CDC recommendation that religious factors be taken into account also violates the Constitutional separation of Church and State, which prohibits the government from coercion in religious matters and from favoring one religion over another.¹⁰⁵ The CDC's draft recommendation that parents should take religion into consideration in making the circumcision decision also favors

⁹⁷ Male circumcision, Global trends and determinants of prevalence, safety and acceptability, UNAIDS, at 1.

⁹⁸ Peter W. Adler, Is it lawful to use Medicaid to pay for circumcision?, 19 J Law Med. 335-53 (2011).

⁹⁹ See, e.g., New Hampshire Criminal statute, RSA 167:61-a ("1. It is a felony crime when a Medicaid provider—with intent to defraud— 2. Submits a false claim for payment; submits a claim for a good or service that was not medically necessary according to professionally recognized standards.")

¹⁰⁰ Draft CDC Recommendations, supra note 1, at 2.

¹⁰¹ Prince v. Massachusetts, 321 U.S. 158 (1944).

¹⁰² See infra notes 112-113.

¹⁰³ See infra Part IV (D) at note 144.

¹⁰⁴ <<http://www.cdc.gov/about/organization/mission.htm>>.

¹⁰⁵ See the Establishment Clause and Free Exercise Clause of the First Amendment to the Constitution of the United States.

Judaism, a fundamental tenet of which is that their god commands circumcision, and Islam, while disfavoring Catholicism, whose doctrine provides that anyone who circumcises another person will be eternally damned, and Christianity, the dominant religion in the United States.¹⁰⁶ Fifth and in any event, physicians are only licensed to perform medical procedures after a diagnosis and recommendation. The American Academy of Pediatrics' ethics committee correctly states the rule that pediatric health care providers:

have legal and ethical duties to their child patients to render competent medical care based on what the patient needs, not what someone else expresses [T]he pediatrician's responsibilities to his or her patient exist independent of parental desires or proxy consent.¹⁰⁷

As Merkel and Putzke have written, "It is obvious that there can be no legal right granting unfettered permission to intrude into another's body simply at one's discretion".¹⁰⁸ The CDC is advising professional doctors, not witch doctors.

Finally, the CDC has not acknowledged, let alone addressed, the arguments legal scholars have been making for at least the past thirty years¹⁰⁹ that it is unlawful for physicians to operate on healthy boys.

C. Lack of Fully Informed Parental Consent

If physicians follow the draft CDC guidelines, parents will not be giving fully informed consent to circumcision as the law requires (e.g., undisclosed conflicts of interest, understated and unknown risks, no disclosure that circumcision may or does impair men's sex lives, no mention of the risk of psychological harm, no mention that circumcision harms all boys and men, exaggerated benefits, and no proof that circumcision reduces HIV in the U.S.). Moreover, physicians routinely take advantage of largely uninformed and trusting parents such as by falsely diagnosing phimosis, not informing them of any risks, and by badgering them to consent.

D. Violation of Boys' Rights

1. *Equal Protection*. Congress made it a criminal offense to cut a girl's genitals or breasts except when medically necessary,¹¹⁰ and thereafter some states enacted similar state statutes.

¹⁰⁶ "Therefore, it commands all who glory in the name of Christ ... to cease entirely from circumcision, since ... it cannot be observed at all without the loss of eternal salvation." Pope Eugene IV, The Council of Florence (A.D. 1438-1445) From Cantate Domino — Papal Bull of Pope Eugene IV (March 16, 2005).

¹⁰⁷ American Academy of Pediatrics, Informed Consent, Parental Permission, and Assent in Pediatric Practice, 95 Pediatrics 314, 315 (1995).

¹⁰⁸ R. Merkel, J. Putzke, J Med Ethics, After Cologne: male circumcision and the law. Parental right, religious liberty or criminal assault? British Medical Journal (June 4, 2013).

¹⁰⁹ See, e.g., William E. Brigman. Circumcision as Child Abuse: The Legal and Constitutional Issues, 23 J Fam Law 337 (1985).

¹¹⁰ 18 U.S.C. Ch. 7, Sec. 116.

The Equal Protection Clause of the U.S. Constitution also applies to the federal government and thus to the CDC through the Due Process Clause of the Fifth Amendment.¹¹¹ Boys have a constitutional right to equal protection of the law.

2. *The Right to Safety and Personal Security.* *The first and principal purpose of government* [and thus of the CDC] under the common law and federal and state constitutional law *is the affirmative duty to protect the safety and health of individuals.*¹¹² The CDC concedes that circumcision risks injury, and as stated, it is always harmful. Thus, the CDC is recommending putting boys and men at risk and harming their health when its duty is to do the opposite. Likewise, the mission, role, and pledge of the CDC, the self-described "nation's health protection agency", is to protect the health and safety of Americans.¹¹³ The Bill of Rights to the United States Constitution similarly prohibits the government, here the CDC, from interfering with the inalienable right of every individual, including every child, to personal security, which includes the right to bodily integrity, of which genital integrity is a subset.

3. *The Right to Liberty (Autonomy and Privacy).* The United States Supreme Court stated in 1891 that no right is held more sacred than a person's "right of complete immunity; to be let alone",¹¹⁴ and to make important choices about one's own body that can be deferred for oneself.¹¹⁵ As the Supreme Court of Montana stated, bodily autonomy is violated by a surgical operation or bodily "invasion" imposed against a person's will.¹¹⁶ Thus, boys and adolescents have both an ethical and legal right to autonomy, or to make the circumcision decision for themselves when they reach the age of legal consent.

4. *The Right to Freedom of Religion.* Under the First Amendment, boys and men have the right upon reaching adulthood to choose the same religion as their parents, if any, another religion, or no religion. As a court in Cologne, Germany held in 2012, circumcision "conflicts with the child's interest of later being able to make his own decision on his religion affiliation".¹¹⁷

5. *A Violation of International Human Rights Law.* Under international law as well, the law of the land in the United States, boys and men have the same rights to personal security, liberty, and equality as they do under American common law and constitutional law.¹¹⁸ Under international

¹¹¹ S. Heyman, *The First Duty of Government: Protection, Liberty and the Fourteenth Amendment*, 41 *Duke L.J.* 507 (1991); Equal protection, Legal Information Institute, Cornell University Law School.

¹¹² *Id.* ("The first duty of the Government is to afford protection to its citizens").

¹¹³ <<http://www.cdc.gov/about/organization/mission.htm>>

¹¹⁴ *Union Pacific Railway Company v. Botsford*, 141 U.S. 250 (1891).

¹¹⁵ *Id.*

¹¹⁶ *Armstrong v. State*, 989 P.2d 364 (Mont., 1999).

¹¹⁷ Quoted in *Europe Goes After Circumcision*, *The Daily Beast* (August 24, 2012).

¹¹⁸ See, e.g., J. Svoboda, *Circumcision of male infants as a human rights violation*, *J Med Ethics* 2013;39:469-474 doi:10.1136/medethics-2012-101229.

law, boys also have the right to be free from prejudicial traditional practices such as circumcision.¹¹⁹ Thus, circumcision violates boys' international human rights.¹²⁰

E. Unlawful for Physicians to Circumcise

As the Royal Dutch Medical Association has written, "The rule [for physicians] is: do not operate on health children".¹²¹ The AAP's ethics committee conceded this in 1995 when it wrote that pediatric health care providers have legal (and ethical) duties to their child patients to render competent medical care based [only] on what the patient needs.

F. Fraudulent

As discussed above, the CDC's draft recommendations and background materials are riddled with illogical, contradictory, false, and misleading medical, ethical, and legal claims and omissions. As will be shown, the CDC also did not comply with the procedural requirements for the issuance of influential medical guidelines. Physicians who follow the CDC recommendations, if implemented, risk suits for actual and constructive or imputed fraud. Under the doctrine of constructive fraud, physicians as fiduciaries are liable for making false statements that gain an unfair advantage over a person—here, boys, men, and their parents—even without knowledge of the falsity of their statements and intent to defraud.¹²²

Several medical groups, physicians, and attorneys have essentially called the draft CDC recommendations and the similar AAP circumcision policy guidelines fraudulent. For example, the 31 distinguished European physicians representing medical associations in Northern Europe commented,

the way from the [CDC's] background paper to the recommendations is marked by *exclusion, omission and minimization of scientific peer evidence that does not support the recommendation*. This is very similar to the development of the AAP circumcision policy statement in 2012 in which *critical evidence was omitted or downplayed*.¹²³

Dr. Van Howe, a peer reviewer, similarly concluded,

... the most remarkable thing is that the CDC is recommending clinicians and health care providers relay information that is *counterfactual, incomplete, and biased* to medical

¹¹⁹ J. Svoboda, Circumcision of male infants as a human rights violation, *J Med Ethics* 1-6 (2013) at 4 & n. 4.

¹²⁰ Cultural Bias, *supra* note 21.

¹²¹ Royal Dutch Medical Association, Non-therapeutic circumcision of male minors (2010).

¹²² J. Steven Svoboda, Peter W. Adler, and Robert Van Howe, Circumcision is Unethical and Unlawful, *The Journal of Law, Medicine & Ethics* (accepted for publication in 2016 after peer review).

¹²³ European CDC Critique, *supra* note 28. See also Cultural Bias, *supra* note 21 ("Recent studies, several of which were not included in the AAP report ... suggest that circumcision desensitizes the penis and may lead to sexual problems in circumcised men and their partners").

decision makers. In essence, they are *deliberately encouraging health care providers to misinform their patients and thus commit medical malpractice [fraud]*.¹²⁴

Bundick states, "medical data from the African circumcision trials are being *inappropriately used* to defend and promote" circumcision: "*Everyone should be told the whole story—a story that does not point to any significant reduction in HIV transmission.*"¹²⁵ The author of this article argued previously that circumcision in general, and the 2012 AAP recommendations in particular, which are similar to the 2014 draft CDC recommendations, *are unlawful and fraudulent*.¹²⁶ Svoboda, Van Howe, and Adler have made the same claim in a peer reviewed article pending publication in a leading journal of medicine, law, and ethics.¹²⁷ Doctors Opposing Circumcision also concluded that the similar 2012 AAP recommendations will mislead the public:

The task force, inadvertently or intentionally, declined to elaborate upon and *withheld from the American public, significant information on the effect of circumcision on sexual function*. ... The AAP has been concerned about state Medicaid agencies denying payment for unnecessary circumcision because its doctors receive less money. ... One apparent purpose for this statement is to re-energize taxpayer-funded Medicaid to allow payment to doctors who perform non-therapeutic, unnecessary circumcisions once again, although it has been argued persuasively that it is unlawful to use Medicaid to pay for unnecessary, elective cosmetic surgery like circumcision. *To increase the income of their members ... these medical associations are willing to put healthy American boys under the circumcision knife and expose them all to the risks of any surgery, and the unique risks, harms, and losses of circumcision itself.*¹²⁸

IV. PROCEDURALLY VALID?

Finally let us ask whether the CDC has met the procedural requirements for the issuance of its proposed guidelines. The draft CDC guidelines are subject to the requirements set forth in a federal statute,¹²⁹ in Executive Orders,¹³⁰ by the Office of Management and Budget ("OMB"),¹³¹

¹²⁴ Van Howe Peer Review, supra note 31, at 4.

¹²⁵ Bundick Critique, supra note 70.

¹²⁶ Peter W. Adler, Is Circumcision Legal?, 16 Rich. J.L. & Pub. Int. 439-83 (2013).

¹²⁷ J. Steven Svoboda, Peter W. Adler, and Robert Van Howe, Circumcision is Unethical and Unlawful, The Journal of Law, Medicine & Ethics (accepted for publication after peer review).

¹²⁸ <http://www.doctorsopposingcircumcision.org/pdf/2013-04-24_Commentary.pdf>, at 8.

¹²⁹ 44 U.S.C. 3506(c)(2)(A) ("provide 60-day notice in the Federal Register").

¹³⁰ Executive Order 13563 -- Improving Regulation and Regulatory Review (January 18, 2011) ("Executive Order 13563").

¹³¹ See OMB Final Information Quality Bulletin for Peer Review ("OMB Quality Bulletin"), <<http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>>.

and by the U.S. Department of Health & Human Services ("HHS").¹³² The draft CDC recommendations and background materials qualify as Highly Influential Scientific Assessments ("HISA"). The CDC explicitly states this in its Peer Review Plan.¹³³ In addition, recommendations are highly influential when, as here, they are "novel, controversial, or precedent-setting".¹³⁴ Moreover, the CDC recommendations would be highly influential if implemented as according to the CDC itself, they would increase the number of surgeries performed on boys and men. Highly influential scientific assessments must comply with stricter requirements set forth in the OMB's Final Information Quality Bulletin for Peer Review.¹³⁵

A. Inadequate Opportunity for the Public to Comment

The OMB states that federal agencies are required to give the public 60 days notice to comment on highly influential proposed guidelines. Executive Order 13563 likewise states that in order to give the public a meaningful opportunity to participate, the comment period should generally be at least 60 days.¹³⁶ The CDC, however, ignored this requirement, and only gave the public and the peer reviewers 45 days to comment.¹³⁷

The CDC also failed to meet the requirement of "sponsor[ing] a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public".¹³⁸ Moreover, given that the CDC has received thousands of comments largely opposed to the draft guidelines, there is an obvious need for a public hearing. There is no indication, however, that the CDC plans to hold one.¹³⁹

B. Guidelines for Peer Review Ignored

When employing a public comment process, as required in this case, the agency is required to provide peer reviewers with access to the public comments.¹⁴⁰ The CDC's Peer Review Plan expressly states and thereby acknowledges that external peer reviewers were not provided with

¹³² HHS Information Quality Web Site, Guidelines for Ensuring the Quality of Information Disseminated to the Public, D. Centers for Disease Control and Prevention ("HHS Guidelines for CDC").
<<http://www.aspe.hhs.gov/infoquality/guidelines/cdcinfo2.shtml>>.

¹³³ Peer Review Plan For Draft CDC Recommendations and The Background, Methods, and Synthesis of Scientific Information Used to Inform the Recommendations for Providers Counseling Male Patients And Parents regarding Male Circumcision in the Prevention of HIV Infection, STIs, and Other Health Outcomes ("Peer Review Plan").
<http://www.cdc.gov/hiv/pdf/policies/MCRecs_PeerReviewPlan.pdf>.

¹³⁴ See OMB Quality Bulletin, supra note 131, at 23.

¹³⁵ Id. ("All other highly influential scientific assessments require a review that meets the requirements of Section III of this Bulletin").

¹³⁶ Executive Order 13563, supra note 130, at 2(b).

¹³⁷ Van Howe Peer Review, supra note 31, at 1.

¹³⁸ OMB Quality Bulletin, supra note 131, at Section III(5).

¹³⁹ Public CDC Comments, supra note 4.

¹⁴⁰ OMB Quality Bulletin, supra note 131.

the public comments.¹⁴¹ (2) Executive Order 13563 also provides, "an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s)." None of this information has been made available to the public.

C. Conflicts of Interest and Bias Not Disclosed

Executive Order 13563 requires that the agency address reviewers' potential conflicts of interest, which appears not to have been done. Similarly, the AAP did not disclose conflicts of interest and bias in its 2012 circumcision policy statement,¹⁴² even though it required those commenting thereon to do so,¹⁴³ as is the norm in medicine.

D. Lack of the Required Objectivity

Executive Order 13563 and the OMB state, "[e]ach agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions."¹⁴⁴ HHS guidelines for the CDC similarly provide,

CDC will ensure that disseminated information meets the standards of quality set forth in the OMB, HHS and CDC guidelines. It is CDC's policy to ensure and maximize the quality, objectivity, utility, and integrity of information that it disseminates to the public. We strive to provide information that is accurate, reliable, clear, complete, unbiased, and useful.¹⁴⁵

This requirement of objectivity precludes the CDC from claiming that parents should take religious, cultural, social, and personal preferences into consideration in making the "circumcision decision". As discussed in this article, the CDC circumcision policy also is not objective, accurate, reliable, complete, or unbiased.

E. No Accurate Assessment of Risk

In addition, when as here there are risks to human health and safety involving influential scientific assessments, HHS guidelines specify that the CDC must use the best available, peer-reviewed science in accordance with sound and objective scientific practices.

In the dissemination of public information about risks, the agency shall ensure that the presentation of information about risk effects is comprehensive, informative, and

¹⁴¹ Peer Review Plan, supra note 133, at 1 ("Peer Reviewers Provided with Public Comments before the Review: No.").

¹⁴² American Academy of Pediatrics Task Force on Circumcision. Circumcision Policy Statement, *Pediatrics*, 130, no. 3 (2012): 585-586 (Liaisons).

¹⁴³ <http://pediatrics.aappublications.org/content/130/3/585/reply#pediatrics_el_54341>.

¹⁴⁴ Executive Order 13563, supra note 130, at Sec. 5.

¹⁴⁵ HHS Guidelines for CDC, supra note 132, at II (emphasis added).

understandable."¹⁴⁶ The CDC must specify, "[e]ach appropriate upper-bound or lower-bound estimate of risk"; "[e]ach significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty"; and "[p]eer-reviewed studies known to the agency that ... fail to support any estimate of risk effects and the methodology used to reconcile the inconsistencies in the scientific data."¹⁴⁷

The draft CDC recommendations do not meet these requirements. They are not comprehensive; they do not provide upper-bound estimates of risks; and the CDC has not cited peer-reviewed studies that fail to support its estimates of risks. The CDC has conceded in its background materials that *it does not know the risks*, but misleadingly, the CDC has failed to disclose this critical fact in its recommendations. The CDC has not reconciled inconsistencies about risks or proposed studies that would resolve uncertainties. Insofar as the CDC does not know the risks, it cannot lawfully recommend that health care providers make circumcision available to anyone, let alone to every newborn boy in the United States and to every heterosexually active adolescent and man not yet circumcised. Disregarding and violating these requirements is another of many acts of deliberate and constructive fraud.

F. Peer Reviews and Comments Not Incorporated

The Peer Review Plan for the draft CDC recommendations provides,

After the initial peer review period, proposed changes to the recommendations resulting from the public comments will be shared with the peer reviewers and peer reviewers will be allowed to provide additional comments at that time. The final documents will be revised to incorporate feedback received from these sources.¹⁴⁸

The CDC is thus required to revise its draft recommendation to incorporate comments received from peer reviewers and from the public. It has not done so, and given that the CDC has not complied with the other procedural requirements for highly influential scientific assessments, it seems unlikely that it will comply with this rule either.

THE IMPLICATIONS AND CONCLUSION

As discussed, the draft CDC recommendations are riddled with innumerable false, misleading, and often contradictory—and thus intentional—medical, ethical, and legal claims, and with procedural flaws that could not have been accidental either. These fatal flaws have been brought

¹⁴⁶ Id. at VII (2) (emphasis added).

¹⁴⁷ Id. at VII (3)(e).

¹⁴⁸ Peer Review Plan, *supra* note 133, at 1.

to the attention of the CDC by a peer reviewer,¹⁴⁹ by the public in thousands of official comments,¹⁵⁰ by European medical associations,¹⁵¹ by an ethicist,¹⁵² and by legal scholars.¹⁵³

The draft guidelines also can be challenged in complaints before several federal agencies, which would have a legal duty to prevent their implementation. In any event, given that the CDC has not followed the procedures required by law for the enactment of highly influential scientific assessments, if implemented, these federal circumcision guidelines would be legally invalid. The guidelines would also be legally invalid because they violate the constitutional rights of the child and the constitutional separation of church and state.

It is too late for the CDC to correct procedural deficiencies (e.g., adequate time to comment, showing the peer reviewers public comments in advance). Thus, the CDC has a duty to withdraw its proposal and to start over with new recommendations.

If the CDC starts over, follows the required procedures, and evaluates the medical evidence alone, as it is required by law to do, it would have to conclude that the prevailing view is correct. Circumcision risks many minor injuries, serious injuries, and death, and harms all boys and men, with little to no prospect of benefiting them. Thus, the disadvantages of circumcision outweigh its unproven, weak, and speculative potential future benefits, not the reverse as the CDC wants parents and men to believe. Moreover, as stated, UTIs can be treated with antibiotics, and boys are not at risk of adult diseases, so to respect their autonomy, they must be left genitally intact so that they can decide for themselves how best to avoid penile cancer and sexually transmitted diseases. In any event, the potential benefits that circumcision may have for men in adulthood can be achieved easily, more effectively, and more safely without it, such as by washing and using a condom.

As the Royal Dutch Medical Association stated, the ethical and legal rule for physicians is, "Do not operate on healthy children"¹⁵⁴ or, it might have added, on healthy men. Men should be told to practice abstinence, monogamy, or safe sex to avoid STIs and HIV. As The Royal Dutch Medical Association concluded, physicians should use their best efforts to *deter* circumcision. The CDC has a duty to give the American public and physicians in the United States the same advice. Physicians who follow the CDC guidelines will mislead parents, adolescent boys, and men about circumcision, and they risk being held liable on many grounds, including fraud, for every circumcision that they perform.

¹⁴⁹ Van Howe Peer Review, supra note 31.

¹⁵⁰ Public CDC Comments, supra note 5.

¹⁵¹ Cultural Bias, supra note 21, and European CDC Critique, supra note 28.

¹⁵² Ear CDC Critique, supra note 57.

¹⁵³ See, e.g., Svoboda JS, Van Howe RS. Out of step: fatal flaws in the latest AAP policy report on neonatal circumcision, *J Med Ethics* (2013), a critique of the similar 2012 AAP circumcision policy statement.

¹⁵⁴ Dutch Position, supra note 122.