Statement by Statement Analysis of the 2012 Report from the American Academy of Pediatrics Task Force on Circumcision: When National Organizations are Guided by Personal Agendas II

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Abstract: In September of 2012, the American Academy of Pediatrics Task Force on Circumcision released its report, which concluded that the benefits of the procedure outweighed the risks. A close analysis of the report reveals the Task Force used a selective, subjective and biased bibliography to support their predetermined conclusions. The Task Force neglected to discuss the anatomy, function, and normal development of the foreskin, nor did they discuss the harm or ethical consequences associated with circumcision. The Task Force deviated from standard practices in its analysis of the medical literature thereby producing a report that falls far below the quality standards set by other AAP policy statements. The report promoted expansion of the procedure as well as the revenue streams for those who perform it. Since release of the report, other national medical organizations have rejected infant circumcision as unwarranted medically and as ethically unacceptable. No organizations outside of the United States have adopted their conclusions. The report is poorly written, poorly researched, makes unsubstantiated claims, and reaches an illogical conclusion.

Introduction

In the weeks following the release of the report from the American Academy of Pediatrics (AAP) Task Force on Circumcision in September of 2012, I went through the report statement and compiled my critique of their statement. I shared this critique with a handful of people at that time. In December 2014, the Centers for Disease Control and Prevention (CDC) subjected their "draft recommendation" to public comment. As a peer-reviewer selected by the CDC, I wrote and submitted a detailed commentary, which can be found at Academia.edu. Given the effort I had previously put into providing a critique of the AAP's 2012 report, it is time to update my analysis of the AAP's misguided statement and distribute it more widely.

General Themes

- 1. Recommendations are predetermined and supported by a selective bibliography.
- 2. There is a failure to adequately research the topics and medical evidence.
- 3. There is a failure to assign the appropriate weight to the evidence with a tendency to give more weight to evidence that supports circumcision and less weight to evidence that does not support circumcision, even between studies of similar design.
- 4. There is a failure to evaluate the quality of individual publications using standard methods.
- 5. There is a failure to recognize or discuss the value and function of the foreskin.

- 6. There is a failure to recognize the value and human rights of the infant.
- 7. Conclusions are reached despite no evidence to support them.
- 8. The report is more reflective of the make-up of the committee rather than medical evidence.
- 9. A key element of this report is to assure that parents can continue to request infant male circumcision, so that physicians can continue to be paid for performing this procedure.
- 10. Consistent disdain is expressed toward males who have an intact penis: the term "uncircumcised" is pejorative, inflammatory, and a form of bias consistent with hate speech.
- 11. There is an underlying racist/anti-immigrant theme.
- 12. Pieces of information are extracted from citations and used to support their agenda, but other pieces of information from the same citation that do not support their agenda are ignored.
- 13. There is a failure to acknowledge studies that do not support the benefits of circumcision.
- 14. The work of scientists who question the validity of the medical benefits of circumcision is routinely attacked.
- 15. The report was two years out of date at the time it was released.

Issues not properly addressed:

- 1. Human rights and bioethics, including the right to an open future.
- 2. The most common complication of circumcision, meatal stenosis, as well as the myriad of other complications.
- 3. The anatomy of the normal, complete, intact penis.
- 4. The histology, anatomy, and function of the foreskin.
- 5. The psychological sequelae of circumcision.
- 6. The harms and risks associated with circumcision.
- 7. Cost utility analysis.
- 8. Contrary evidence and opinions.
- 9. Incidence of phimosis and balanitis in intact boys.
- 10. Non-specific urethritis and the overall risk of sexually transmitted infections.
- 11. The impact of risk compensation.
- 12. Positions taken by other national medical organizations throughout the world.

ABSTRACT

Statement 1: "Male circumcision consists of the surgical removal of some, or all, of the foreskin (or prepuce) from the penis."

Comment: Accurate, but incomplete, and below academic standards. It does not adequately describe the foreskin as functional, erogenous tissue. The Task Force fails to mention the anatomy, histology, physiology, or sexual functions of the foreskin. This is unacceptable since most medical reviews and discussions begin with a complete scientific discussion of the basic anatomy, histology, and physiology in regards to the organ, or disease, being discussed before moving on to other topics of pathophysiology, disease, epidemiology, and treatment. In the 1984 AAP pamphlet "Care of the Uncircumcised Penis" the functions of the foreskin are discussed. In

subsequent versions of the same pamphlet dropped the discussion of the functions of the foreskin as though they never existed. When contacted, officials from the AAP are unable identify why this information was removed from the pamphlet.[http://www.circumcision.org/pamphlet.htm]

Statements 2 and 3: "It is one of the most common procedures in the world. In the United States, the procedure is commonly performed during the newborn period."

Comment: **Misleading.** Only accurate in the United States, Israel, and Muslim countries. Few male circumcisions are performed worldwide as only about 15-20% of the world performs them. Most circumcisions worldwide are performed on older children.

Statement 4: "In 2007, the American Academy of Pediatrics (AAP) convened a multidisciplinary workgroup of AAP members and other stakeholders to evaluate the evidence regarding male circumcision and update the AAP's 1999 recommendations in this area. The Task Force included 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."

Comment: **Inaccurate**. Not all stakeholders were present in evaluating the evidence. The workgroup did not appear to include any men who were not circumcised or any members who were known to be skeptical of the practice of infant circumcision, or any representatives of groups opposing circumcision. This workgroup represented a classic example of '*group think*' in which a group of like-minded people will agree to more extreme positions than they would take individually.[Sunstein & Hastle 2014] Research has shown that circumcised physicians are five times more likely to recommend circumcision to the families of the patients they care for, and physicians whose own children are circumcised are six times more likely to recommend circumcised are six times more likely to recommend circumcision to their patients. [Muller 2010] With a Task Force where all of its membership fell into these categories, is it any wonder that they produced a document favoring the continuation of infant circumcision, even though the majority of medical evidence does not support it? It is also worth noting that, unlike other AAP Task Forces and working groups,[Wald et al 2013, Lieberthal et al 2013, Subcommittee on Urinary Tract infection 2011] this Task Force did not include any members with established expertise on the topic of interest.

Statement 5: "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."

Comment: **Inaccurate**. As will be noted below, they conducted a biased review of the peerreviewed literature. As will be shown in this commentary, key articles that were inconsistent with the pro-circumcision agenda of the Task Force were excluded. The AHA's template is not the standard for evidence evaluation that had previously been adopted by the AAP [AAP Steering Committee 2004] or the widely-accepted and used standard established by the Oxford Centre for Evidence-Based Medicine [Oxford Centre]. This change deviated from the standard approach for the interpretation of studies.

Recommendation A: "Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks; furthermore, the benefits of newborn male circumcision justify access to this procedure for families who choose it."

Comment: Unsubstantiated conclusion. As noted later in the report, the risks of circumcision remain largely unstudied and unknown. Therefore, how can the health benefits of newborn circumcision outweigh the risks when the risks are unknown? Likewise, many of the benefits attributed to newborn male circumcision come from studies (themselves of questionable validity) involving adult male circumcision while there is no evidence these benefits can be attributed to *newborn* male circumcision. The second half of this statement reveals the true motive behind this conclusion: to assure that circumcisions are still performed and paid for, so that physicians can continue to receive financial compensation often at taxpayer expense. In order to make this claim they need to do a formal cost-utility analysis. They did not. A 2006 cost analysis of circumcision found that circumcision did not save money.[ref 234] A cost analysis of the impact of circumcision on HIV infection is cited by the Task Force, [ref 60] but this analysis made assumptions based on African studies that have not been replicated in the United States. Like any model, this one suffered from the problem of garbage-in=garbage-out.[Anderson 2010, Van Howe 2010] The Task Force ignored a thorough cost-utility analysis that found that, over the course of a lifetime, the assumptions could not be manipulated to make circumcision less costly than forgoing circumcision, and that there was an overall negative impact on health.[Van Howe 2004] Without doing their own analysis, and with nothing new in the medical literature that is not considered by the sensitivity analyses performed in previous analyses, there is no objective evidence on which to base their conclusions. Consequently, the only alternative explanation is that the Task Force based this recommendation on their personal beliefs. The conclusion that families can choose circumcision because the benefits outweigh the risks is a *non sequitur*. Other factors, such as ethics and human rights, need to be considered. There are many examples of procedures where the benefits may slightly outweigh the risks, but these procedures are not performed on non-consenting individuals.

Statement 7: "Specific benefits from male circumcision were identified for the prevention of urinary tract infections, acquisition of HIV, transmission of some sexually transmitted infections, and penile cancer."

Comment: Inaccurate. These will be addressed in the appropriate sections that follow.

Statement 8: "Male circumcision does not appear to adversely affect penile sexual function/ sensitivity or sexual satisfaction."

Comment: **Blatantly false, incomplete**. Will be discussed below. The Task Force failed to consider the full breadth of the evidence.

Statement 9: "It is imperative that those providing circumcision are adequately trained and that both sterile techniques and effective pain management are used."

Comment: **Partially accurate and unclear**. Sterile techniques are essential. Safe, effective pain management options are not available for infant male circumcision (as will be discussed below). Does this recommendation for "adequately trained" practitioners apply to *mohelim* for whom there is no certification process, thus no assurance that they are "adequately trained?" When a *mohel* circumcises an infant male, is he practicing medicine without a license? Does this mean that the AAP is calling for the certification of adequate training of *mohelim*? Is the AAP hoping to stop *mohelim* from performing circumcisions? Does this mean that the AAP does not support the current California statute that places no restrictions on who can perform a circumcision?

Statement 10: "Significant acute complications are rare."

Comment: **Unclear**. **Insubstantial evidence**. The term "significant" is a term usually reserved for use following statistical evaluation and its use is inappropriate here. How bad does a complication need to be to be considered "significant?" Likewise, below what level of prevalence or incidence is something considered "rare." Also, with acknowledgement that complications have been poorly studied, how can this claim be made conclusively? With three vague, imprecise terms in this statement, it has no clear meaning. As will be discussed later, the decision to exclude case reports and case series from consideration biased their perception about the incidence and impact of acute complications.

Statement 11: "In general, untrained providers who perform circumcisions have more complications than well-trained providers who perform the procedure, regardless of whether the former are physicians, nurses, or traditional religious providers."

Comment: **Insufficient evidence**. This may be a scare tactic to keep circumcisions and the money generated within the fold of the medical profession. This topic has received relatively little study. One study of Family Medicine residents found no difference in complication rates based on their years of training,[Moreno & Realign 1989] while those learning to circumcise adults in Africa demonstrated a long learning curve.[Kiggundu et al 2009] There are numerous cases of complications reported in the medical literature from circumcisions performed by trained medical providers using standardized techniques in hospital settings throughout the U.S., and the majority of circumcisions in the US are done in hospitals.

Recommendation B: "Parents are entitled to factually correct, nonbiased information about circumcision and should receive this information from clinicians before conception or early in pregnancy, which is when parents typically make circumcision decisions."

Comment: **Potentially unethical**. While parents should receive factually correct, nonbiased information, the information contained in this report or the "draft recommendation" of the CDC

would be factually inaccurate and biased. Therefore, physicians should not rely on this information. As stated, this allows for the solicitation of unnecessary surgery.[AMA 1997] Because unsolicited inquiries regarding circumcision can be interpreted as a recommendation, [ref 18, Svoboda et al. 2000] this information should only be given if the parents request the information. If circumcision is not mentioned by parents, it should not be discussed by the physician.

<u>Update</u>: Subsequent to the AAP's last literature search, a study found that circumcised providers were five times more likely to recommend circumcision to their patients and providers with circumcised sons were six times more likely to recommend circumcision. The ability to give unbiased information may be impacted by circumcision status of the provider and their family members.[Muller 2010] It could be argued that the same sort of bias impacted the membership of the Task Force and the Centers for Disease Control and Prevention.[Frisch et al 2013]

Statement 13: "Parents should determine what is in the best interest of their child."

Comment: **Inconsistent with other AAP policy**. In the 1995 position statement of the Committee on Bioethics, physicians have an obligation to consider the best interests of the child, who is their patient, and should not be persuaded by parents if parents decide they want to do something that the physician believes is not in the best interests of the child.[ref 9]

Statement 14: "Physicians who counsel families about this decision should provide assistance by explaining the potential benefits and risks and ensuring that parents understand that circumcision is an elective procedure."

Comment: **Inconsistent with other AAP policy**. The 1995 Committee on Bioethics position stated that elective procedures that can safely wait until the child is old enough to provide informed consent should be delayed until that time.[ref 9] Circumcision fits this definition. Physicians and parents cannot fully understand the risks because, based on the contents of this report, the AAP doesn't fully know what the risks are.

Statement 15: "The Task Force strongly recommends the creation, revision, and enhancement of educational materials to assist parents of male infants with the care of circumcised and uncircumcised penises. The Task Force also strongly recommends the development of educational materials for providers to enhance practitioners' competency in discussing circumcision's benefits and risks with parents."

Comment: **Accurate, but incomplete**. The Task Force should also recommend the development of educational materials and curriculum that educates practitioners in the anatomy, physiology, development, and sexual function of the foreskin, as soon as the task force learns what they are. The vast majority of practitioners are woefully ignorant on these topics. The bias of the AAP Task Force is clearly evident and skewed towards the surgical removal of the foreskin, not towards educating physicians and parents about the inherent value of the foreskin, a normal part

of male anatomy. No other normal body part is treated in this manner by the AAP. The Task Force should also recommend that terms such as "uncircumcised," which are considered by many males with an intact penis, to be pejorative, derogatory, and, in some instances, racist and anti-immigrant, be avoided.[Wallace 2015] The Task Force's disregard for the use of such terms with negative connotations, and their failure to use less inflammatory terminology, is evidence of their underlying cultural bias. If a political group released a statement, which included contemptuous, inflammatory, pejorative, racial slurs, would they not be considered biased? The use of the term "uncircumcised" is a red flag for biased content. Again, the full complement of risks cannot be addressed because they are unknown and are not adequately covered by this policy statement, as will be discussed.

Recommendation C: "Physicians counseling families about elective male circumcision should assist parents by explaining, in a nonbiased manner, the potential benefits and risks and by ensuring that they understand the elective nature of the procedure."

Comment: **Potentially unethical**. See Statement 13. This policy statement is biased, so it would be impossible for any physician using this statement to present unbiased information, if they are relying on this report for accurate information. Furthermore, elective surgeries should not be performed on persons who cannot consent to the surgery. Circumcision is an elective cosmetic alteration of normal anatomy. As such, it is solicitation of an unnecessary procedure for physicians to even broach the subject. The AAP is on shaky ground stating that the benefits outweigh the risks in a thinly veiled attempt to change the paradigm to one that infers some justification for or supposed "benefit" from circumcision.

Recommendation D: "Parents should weigh the health benefits and risks in light of their own religious, cultural, and personal preferences, as the medical benefits alone may not outweigh these other considerations for individual families."

Comment: **Evasion**. Like the 1999 Task Force, [ref 1] the current Task Force does not want to take on the responsibility for determining the weight of the health issues. They want to transfer this decision to someone else, so if bad things happen (and from a medical standpoint with purely cosmetic surgeries, such as circumcision, only bad things can happen) they can blame it on the parents. This also appears to expand the role of physician to include that of cultural broker, which is not within the ethical duties of a physician. [AMA, 1997] This transfer of responsibility reflects a lack of courage, and a reliance on cultural relativism, on the part of the Task Force. Either it is indicated medically or it is not. Either the infant has human rights worthy of protections or he is the property of the parents. The Task Force needs to explain and justify taking this position. It should be noted that the Committee on Bioethics, then chaired by Task Force member Douglas Diekema, relied on cultural relativism to justify their endorsement of some forms of female genital cutting. [Committee on Bioethics 2010] This policy was not well received and resulted in the policy being retired a month later. [Van Howe 2011]

Recommendation E: "Parents of newborn boys should be instructed in the care of the penis, regardless of whether the newborn has been circumcised or not."

Comment: **Incomplete**. Most medical professionals who take care of children do not know how to care for the intact penis: namely that it should not be retracted. The Task Force should have included in its recommendation that medical professionals be instructed in the anatomy, physiology, development, sexual function, and care of the normal penis, which includes the foreskin. This should have been the primary focus of this committee rather than focusing on revenue streams.

Recommendation F: "Elective circumcision should be performed only if the infant's condition is stable and healthy."

Comment: **Inconsistent with other AAP policy, incomplete**. See Statement 14. What or who determines if the infant's condition is stable and healthy? There has been a debate over whether children with heart defects should be circumcised because of the risk of transient bacteremia. [Storms 1998] This issue needs to be explored further and needs an explicit definition. Considering that it is an "elective" procedure, it should not be performed without the *patient*, not his proxies, providing fully informed consent. There are cases reported of infants in the NICU who suffered severe complications as a result of circumcision. Should infants in the NICU be circumcised since they clearly aren't 'healthy' if they are in the NICU? Should preterm infants be circumcised? Should testing be done for hemophilia and other blood disorders prior to circumcision? Bad things happen when normal healthy tissue is disturbed without indication.

Recommendation G: "Analgesia is safe and effective in reducing the procedural pain associated with newborn circumcision; thus, adequate analgesia should be provided whenever newborn circumcision is performed."

Comment: **Inconsistent with other AAP policy**. As will be discussed later, the analgesia provided is incomplete and inadequate. While it may reduce the procedural pain when these agents are used, the procedure is still painful and stressful. AAP policy is that infants should be afforded the same pain relief that is given to older children and adults.[Poland et al, 1987, Committee on Fetus and Newborn, 2000] Older children and adults are given general anesthesia because it provides adequate anesthesia. Again, no elective circumcision should be performed on an infant, and there are no indications for non-elective circumcision in a newborn.

Recommendation H: "Nonpharmacologic techniques (eg, positioning, sucrose pacifiers) alone are insufficient to prevent procedural and post-procedural pain and are not recommended as the sole method of analgesia. They should be used only as analgesic adjuncts to improve infant comfort during circumcision."

Comment: Appropriate.

Recommendation I: "If used, topical creams may cause a higher incidence of skin irritation in low birth weight infants, compared with infants of normal weight; penile nerve block techniques should therefore be chosen for this group of newborns."

Comment: **Incomplete**. As discussed below, penile nerve block techniques do not provide adequate anesthesia, and circumcision is not medically indicated in healthy infants. Topical creams are associated with adverse outcomes, such as methemaglobinemia from EMLA® cream, [Cade & Shollenberger 2003,Elsner & Dummer 1997, Mandel 1989, Tse et al 1995, Özbek& Sarikayalar 1993, Prunes et al 1997, Ford & Agnew 1972, Jakobson & Nilsson 1985, Boran et al 2008, Ozdogan et al 2010, Akbayram et al 2012, Arda et al 2000] and these creams are not adequate for anesthesia in any patient.

Recommendation J: "Key professional organizations (AAP, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Society of Anesthesiologists, the American College of Nurse Midwives, and other midlevel clinicians such as nurse practitioners) should work collaboratively to:

Develop standards of trainee proficiency in the performance of anesthetic and procedure techniques, including suturing;"

Comment: **Incomplete**. While these are important techniques to learn for any number of procedures, infant circumcision is an elective procedure, which should not be performed as per AAP bioethical policies.[ref 9] This report is all about increasing the demand to keep the money rolling in. There is also the need to address the issue of conscientious objectors.[Storms 2013]

Recommendation K : "Teach the procedure and analgesic techniques during post-graduate training programs;"

Comment: **Incomplete**. Despite the fact that non-elective procedures should not be performed on infants or children, this may be taught in post-graduate training programs, but it should not be a requirement. For example, the current requirements from the Accreditation Council for Graduate Medical Education (ACGME) for the training of residents in Pediatrics notes that "Residents must demonstrate knowledge of established and evolving biomedical, clinical, epidemiological and social-behavioral sciences, as well as the application of this knowledge to patient care. Residents: ... must be competent in the understanding of the indications, contraindications, and complications for the following: ... circumcision" (IV.A.5.b).(2).(d)).[ACGME 2013] Residents are not required to learn to perform or perform the procedure. The Task Force recommendations go beyond what is currently the policy of the ACGME. Residents should be afforded the opportunity to be conscientious objectors and have this wish respected. These residents should not be harassed or assigned additional duties for taking this position.[Storms 2013] Why should we teach analgesic techniques that we know do not provide adequate anesthesia? This only results in a procedure that is both unnecessary and unnecessarily painful.

Recommendation L: "Develop educational materials for clinicians to enhance their own competency in discussing the benefits and risks of circumcision with parents;"

Comment: **Appropriate**. However, non-elective cosmetic procedures should not be solicited or performed on children. This should also include education regarding the anatomy, histology, physiology, and sexual function of the foreskin because only a small percentage of health care professionals have any knowledge of the structure and function of the normal, intact penis complete with a foreskin.

Recommendation M: "Offer educational materials to assist parents of male infants with the care of both circumcised and uncircumcised penises."

Comment: **Appropriate but incomplete**. Inflammatory language, such as "uncircumcised" should not be used in these materials. That would be akin to referring to females with breasts as "unmastectomized" and providing parents with materials on how to care for unmastectomized breasts. Similarly is a female who has not be circumcised "unclitoridetomized."

Recommendation N: "The preventive and public health benefits associated with newborn male circumcision warrant third-party reimbursement of the procedure."

Comment: Unsubstantiated and Inappropriate. Alerts readers to the Task Force's true underlying motivation. This recommendation, repeated throughout the report, sticks out like a sore thumb and reflects poorly on the Task Force and the AAP. Without knowing the true motivation behind the formation of this Task Force, it is probably more than a coincidence that the Task Force was formed after several states decided, for financial reasons, to no longer have their Medicaid programs reimburse healthcare providers for performing circumcisions on infant males. Other AAP statements do not beg for money in this fashion. For this Task Force to do so makes it look biased and unethical. If the AAP is looking out for the financial health of its membership, reimbursement for circumcision should be on the basis of the medical evidence, not random, unsupported recommendations. The fact that the Task Force felt compelled to repeatedly beg for reimbursement indicates their belief that the selective evidence they presented would not be enough to convince legislatures to spend their limited resources on infant male circumcision. This is a diversionary tactic designed to sway opinion away from the fact that there are no preventive or public health benefits associated with newborn male circumcision. Even if there were these benefits, the Task Force would need to demonstrate they deserve third-party reimbursement. Practitioners know that third-parties do not automatically reimburse for every intervention or procedure that has purported benefits. Third-parties have a history of reimbursing for those interventions that appear to be the most cost-effective. The Task Force has made no effort to show, in general, that infant circumcision is cost effective. They cite a cost analysis that found infant circumcision does not recoup its costs and loses money.[ref 234] They failed to cite a cost-utility analysis that showed that infant circumcision is more costly than not circumcising. [Van Howe 2004] In an incomplete analysis that is based on questionable assumptions, including an overestimation of HIV incidence and an unsubstantiated belief that the results of the African

Analysis of 2012 AAP Task Force on Circumcision Report

trials in adult males would apply to North American infants, it was found that infant circumcision was cost-effective for preventing HIV in Hispanics and African-Americans, but not Caucasians. [ref 60] To justify third party reimbursement, the Task Force also needs to demonstrate that infant circumcision is more effective, less costly, or less invasive than alternative therapies. They failed to even attempt to demonstrate this because it is impossible. For example, it would cost less to put every boy on prophylactic antibiotics for the first six months of life than to circumcise all of them. Countries that do not routinely circumcise don't do this because that is also not cost effective and too invasive, even though it is more cost-effective and less invasive than infant circumcision. Sexually transmitted diseases are better prevented through regular surveillance, prevention with condom use, and treatment when needed. For the cost of a circumcision, one can buy enough condoms to last a couple of life times. Condoms are less expensive, more effective, and less invasive than circumcision in preventing sexually transmitted infections. Furthermore, condoms are more likely to slip off when used by a circumcised man, thus undermining their effectiveness.[Richters, Gerofi, & Donovan 1995a] For HPV infections, there is an effective vaccine, the use of which does not involve the removal of any body parts. It is also much more effective clinically, more cost effective, and less invasive. For HIV infections, if you believe the model in Reference 60, in which infant circumcision was only cost effective in African American and Hispanic infants you would need to conclude that Caucasian infants should not receive third party reimbursement. But when compared to secondary prevention methods (treatment with antiretroviral therapy, pre-exposure prophylaxis, and condom use), infant circumcision is more costly, less effective, and more invasive. To prevent one case of penile cancer in an octogenarian would cost millions of dollars. The vaccine for HPV and treatment of phimosis would be much more effective and less costly. So, when third party payers look at whether to reimburse infant circumcision, there is no compelling reason for them to do so because there are more effective, less expensive, less invasive options available.

<u>Update</u>: It has been argued that it is illegal for any states to pay for infant male circumcision. [Adler 2011]

Statement 16: "The American Academy of Pediatrics' (AAP) statement on circumcision of the newborn penis was last issued in May 1999."[1]"

Comment: Accurate.

Statement 17: "The Circumcision Policy Statement recognized the health benefits of circumcision but did not deem the procedure to be a medical necessity for the well-being of the child."

Comment: **Misleading**. This gives a very positive spin to the 1999 Task Force report. The Task Force would have been better served to quote the 1999 Task Force: "there may be some benefits, but there is no evidence to recommend RIC."[ref 1]

Statement 18: "Since that time, substantial contributions have been made to the peer-reviewed literature concerning circumcision of males and its possible benefits."

Comment: **Hyperbole**. Contributions may have been made, but adding "substantial" to modify "contributions" is hyperbolic. Also contributions about the harms have been added to the literature since the Task Force last looked at the medical literature in 2010, but these are largely ignored by the Task Force.

Statement 19: "For this reason, in 2007, the AAP formed a Task Force charged with reviewing current evidence on male circumcision and updating the policy on this procedure to provide guidance to AAP membership regarding the circumcision of newborn males."

Comment: **Inaccurate**. Makes it sound as though they were commanded by God to make sure all understand why this must be done...., yet they failed in their charge as they only *selectively* reviewed the current evidence on male circumcision.

Statement 20 : "Male circumcision consists of the surgical removal of some, or all, of the foreskin (or prepuce) from the penis."

Comment: Accurate but incomplete. See Statement 1.

Statement 21: "It is one of the most common procedures in the world. In the United States, the procedure is most frequently performed during the newborn period."

Comment: **Misleading**. Using the term "procedure" gives the impression that circumcision is considered a "surgical operation" around the world, when in fact most circumcisions are performed as a cultural or religious ritual. This statement may also give the impression that circumcision is spread evenly around the world when, in fact, most societies have either very high or very low circumcision rates. For all practical purposes circumcision is only considered a "procedure" in the United States, Canada, and Australia.

Statement 22: "Elective circumcision performed soon after the newborn period is generally a result of deferral because of low birth weight or illness in the newborn. Circumcision after the newborn period is most commonly performed because of the infant's low birth weight or illness precluded newborn circumcision."

Comment: **Unclear and undocumented**. This statement implies that all infants/parents favor the state of being circumcised and that a failure to be circumcised in the newborn period is an oversight or can be blamed on some factor such as LBW or illness. This is a preposterous stretch on the AAP committee's part. Elective circumcision is performed at parental request. What is meant by "soon after the newborn period"? Is this after 28 days of age or is this after the perinatal hospitalization? Citations for this fact exist, but were not included.[ref 192]

Statement 23: "Other infants are circumcised later in life because of the occurrence of tight phimosis and/or urinary tract infection (UTI)."

Comment: **Undocumented**. No citation given. Most infants circumcised later in life are circumcised for religious reasons, primarily in the Islamic tradition. A tight foreskin alone is not an indication for circumcision. Pathological phimosis, typically from balanitis xerotica obliterans, that does not respond to topical steroid application, is one of the only medical indications for circumcision. The cumulative risk for pathologic phimosis by 15 years of age is 0.6% in Britain[Shankar & Rickwood 1999] and 0.42% in China.[Lau & Ching 1982] Phimosis is often used as a diagnosis in a patient with a normal foreskin in order to secure reimbursement for circumcisions that are requested for cultural or cosmetic reasons.[Larsen & Williams 1990] Less than 1% of boys will ever have a UTI, and having a UTI is not an indication for circumcision. Children are circumcised in the U.S. primarily because physicians don't know how else to deal with penile problems that occur, or because of pressure from physicians who know little or nothing about foreskin care/anatomy/structure/function.[Larsen & Williams 1990] UTI's are not caused by the presence of the foreskin, but by bacteria. Phimosis can be treated with topical steroids (85% effective) or less invasive surgeries.[Van Howe 1998]

<u>Update</u>: The 2014 data from Hart-Cooper et al. point out that American physicians diagnose phimosis about one thousand times more commonly than physicians in Britain. In the first year of life, boys in the United States are circumcised for "phimosis" at a rate of 2247.7 per 100,000 person-years (95%CI=2355.5-2142.9)[Hart-Cooper et al 2014]compared to 1.97 per 100,000 person-years (95%CI=0.278-14.012) in Britain[Shankar & Rickwood](RR=1138.31; 95%CI=160.26-8086.09). Either physicians in the United States do not know how to diagnose phimosis, or the diagnosis is used to secure reimbursement for elective circumcisions, or both. To minimize this potential fraud, insurance companies should not pay for circumcisions in children under the age of five unless the child has failed a course of steroids and has had the diagnosis of balanitis xerotica obliterans confirmed by biopsy. The 2015 data from a Scottish study found that only 3 of 180 (1.7%) males aged 0 to 16 years with a documented UTI were circumcised because of UTI recurrences.[Broadis et al. 2015] Given that 1% of males will develop a UTI one would expect that only 1 in 6000 would be circumcised related to UTIs.

Statement 24: "The 3 most common operative methods of circumcision for the newborn male include: the Gomco clamp, the Plastibell device, and the Mogen clamp (or variations derived from the same principle on which each of these devices is based)."

Comment: **Incomplete**. Mogen clamp is currently bankrupt following judgments in product liability cases of over \$10 million for amputated glans and other complications.[D.P. Jr v Kendall and Sonya 2006]

Statement 25: "The elements that are common to the use of each of these devices to accomplish circumcision include the following: estimation of the amount of external skin to be removed; dilation of the preputial orifice so that the glans can be visualized to ensure that the glans itself is

Analysis of 2012 AAP Task Force on Circumcision Report

normal; bluntly freeing the inner preputial epithelium from the epithelium of the glans; placing the device (at times a dorsal slit is necessary to do so); leaving the device in situ long enough to produce hemostasis; and removal of the foreskin."

Comment: Accurate, but irrelevant.

Statement 26: "The extent of this practice in the United States has been estimated by various federally sponsored national surveys, each of which has its strengths and limitations; thus, multiple measures of circumcision prevalence and incidence are presented. There are large population measures of male circumcision in the United States, measuring either the occurrence (ie, incidence) of male circumcision among newborns or the existence of the circumcised state among representative samples of males in the United States at a particular period in time (ie, prevalence). The findings of these studies are qualitatively similar and consistently estimate the rate of male circumcision to range from 42% to 80% among various populations.[2–6] A recent Centers for Disease Control and Prevention (CDC) study assessed trends in the incidence of in-hospital newborn male circumcision from 1999 to 2010 using 3 independent sources of discharge data on in-patient hospitalizations: the National Center for Health Statistics' National Hospital Discharge Survey (NHDS), the Agency for Health-care Research and Quality's National Inpatient Sample (NIS), and the SDI Health's Charge Data Master (CDM).[2,3] These sources were used to estimate the incidence of newborn male circumcision in the first month of life. Overall from 1999 to 2010, the CDC's weighted analysis found that the approximate percentage of newborn US males who were circumcised was approximately 59.1% according to the NHDS, 57.8% according to the NIS, and 55.8% according to the CDM. The incidence of newborn male circumcision decreased over time in all 3 data sources: from 62.5% in 1999 to 56.9% in 2008 according to the NHDS; from 63.5% in 1999 to 56.3% in 2008 according to the NIS; and from 58.4% in 2001 to 54.7% in 2010 according to the CDM (Fig 1). A key limitation is that these incidence rates were derived from hospital-based surveys and do not include out-of-hospital circumcisions; thus, these data sources underestimate the actual rate of newborn male circumcision in the first month of life.

NIS

The NIS is a database of 5 to 8 million hospital inpatient stays drawn from states that participate in the Healthcare Cost and Utilization Project (HCUP). In 2008, these states comprised 95% of the US population. The NIS is used to track and analyze national trends in health-care utilization, delivery, and outcomes via a 20% stratified sample of 1000 community hospitals. Weights are provided to calculate national estimates.[4]

The NIS indicates that circumcision was performed in 57% of male newborn hospitalizations between 1998 and 2005. NIS data from 1988 to 2008 indicate that the rate of circumcision performed during newborn male delivery hospitalizations increased significantly from 48% in 1988–1991, to 61% in 1997–2000,[5] then declined from 61% to 56% in 2000–2008[6] (Fig 1). Circumcision rates were highest in the Midwestern states (74%), followed by the Northeastern

(67%) and Southern states (61%). The lowest circumcision rates were found in the Western states (30%) (Table 1).[3]

NHANES

The NHANES provides a snapshot of the health and nutritional status of the US population aged 14 to 59 years at the time of the survey, by using a probability sample of persons aged 0 to over 60 years. Prevalence of male circumcision is derived from participant self-report and is thus subject to misclassification. From 1999 to 2004, NHANES found that, of the 6174 men surveyed, 79% of men reported being circumcised, including 88% of non-Hispanic white men, 73% of non-Hispanic black men, 42% of Mexican-American men, and 50% of men of other races/ethnicities[6] (Fig 2).

However, prevalence rates are limited by the accuracy of the examiner and/or the self-report. [7,8] These findings underscore the necessity of using a standardized clinical examination for establishing circumcision status for the purpose of research on circumcision. It also highlights the potential difficulty of advising on care of the circumcised and uncircumcised penis when an individual and/or clinician may not know which condition is present."

Comment: Accurate, unnecessary, inflammatory, uninteresting. Long discussion that is not of much interest. The data collection methods make any of these estimates suspect. If the Task Force provided this long section on epidemiology of circumcision, why could they fail to discuss the anatomy, histology, physiology, and sexual function of the body part being amputated? Since when is being circumcised or having an intact penis a "condition"?

Statement 27: "The practice of medicine has long respected an adult's right to self-determination in health care decision-making."

Comment: **Incomplete**. This right also extends to all humans, regardless of age. Then why is the infant and child's right to self-determination not being respected by this policy?

Statement 28: "This principle has been operationalized through the doctrine of informed consent. The process of informed consent obligates the clinician to explain any procedure or treatment and to enumerate the risks, benefits, and alternatives so the patient can make an informed choice."

Comment: **Incomplete**. The informed consent process also includes confirming that the decision-maker understands what has been told and that the patient is willing to undergo the intervention voluntarily, without coercion.[Etchells et al 1996a, Etchells et al 1996b, Etchells et al 1996c, et al 1996d]

Statement 29: "As a general rule, minors in the United States are not considered competent to provide legally binding consent regarding their health care, and parents or guardians are empowered to make health care decisions on their behalf.[9]"

Comment: **Misleading**. This is true when there is a specific disease or health concern that requires a medical decision be made. This is not true when an elective cosmetic procedure is being considered. It is the position of the AAP that without a legitimate diagnosis, or a pressing health concern that cannot be delayed, parents are not empowered to make health care decisions on the behalf of their children.[ref 9] Why did the Task Force only read parts of this policy and ignore the parts that they don't like? It can be easily demonstrated that infant circumcision is not health care, so parental empowerment does not apply.

Statement 30: "In most situations, parents are granted wide latitude in terms of the decisions they make on behalf of their children, and the law has respected those decisions except where they are clearly contrary to the best interests of the child or place the child's health, well-being, or life at significant risk of serious harm.[10]"

Comment: **Incomplete**. Reference 10 is a paper written by one of the Task Force members that reflects *his* opinion, which is that instead of considering the best interests of the child, we should instead use the "harm principle." Basically, the harm principle states that parents can do whatever they like with their children as long as the detected harm does not rise above some arbitrary threshold. The report fails to mention that most ethicists would argue that parents are not allowed to violate the basic human rights of their children.[Dwyer 2006] Diekema is in the minority, as his writing and sworn testimony indicate that he believes children do not have rights. [Mayes 2010] The rights of children have been well established internationally.[Convention on the Rights of the Child 1989, Commission on human rights 1987, Universal Declaration of Human Rights 1948] Diekema's position of minimizing the value of the rights of children is also inconsistent with AAP Mission Statement — "to attain optimal physical, mental, and social health and wellbeing for all infants, children, adolescents, and young adults. To accomplish this mission, the AAP shall support the professional needs of its members." (Based on the emphasis given to the financial reimbursement for performing circumcisions, the Task Force appears to have been collaborating to support the financial needs of its members.)

<u>Update</u>: The limited role of parental authority has been addressed in more detail since the Task Force last searched the medical literature.[Dwyer 2011, Van Howe (JME) 2013]

Statement 31: "Parents and physicians each have an ethical duty to the child to attempt to secure the child's best interest and well-being.[11]"

Comment: **Incomplete**. Parents also have an ethical duty to protect the child's basic human rights.[Rawls 2001, Dwyer 1994, Dwyer 2006, Dwyer 2011, Van Howe (JME) 2013] Removal of normal healthy body parts is not in the child's best interest and adversely affects their well-being. The Task Force did not address the harm associated with amputation of the foreskin. There is ample documentation of this harm that they chose to ignore.

Statement 32: "Reasonable people may disagree, however, as to what is in the best interest of any individual patient or how the potential medical benefits and potential medical harms of circumcision should be weighed against each other."

Comment: **Incomplete**. There is nearly universal consensus as to the basic human rights to which all humans are entitled. One of the rights is the right to bodily integrity and security of person. Some of these concerns can be addressed if an approach of substitute judgment is used. In this process, it is asked what would the incompetent person choose for themselves if competent.[Lebit 1992, Dwyer 2006] Diekema dismisses this approach out of hand without discussion as such an approach respects and forwards the rights of incompetent people.[ref 10]

<u>Update</u>: This issue has been further explored by Svoboda [2013].

Statement 33: "This situation is further complicated by the fact that there are social, cultural, religious, and familial benefits and harms to be considered as well.[12]"

Comment: **Unsubstantiated, inconsistent with other AAP policy**. Reference 12 notes that many consider these other factors when deciding on infant circumcision, but makes no case that these factors SHOULD be considered by physicians or families. In the 1998 AAP's position on female genital cutting, social, cultural, religious, and family beliefs are not a consideration: no cutting of the genitals in minor females is allowable for these reasons.[Committee on Bioethics 1998] In 2010, a revised report on female genital cutting was generated by the AAP Committee on Bioethics, which was chaired by one of the Task Force members. It included a recommendation that forms of female genital cutting that were less severe than the most common form of male circumcision were permissible, even though they are currently illegal.[Committee on Bioethics 2010] A backlash to the report resulted in it being "retired" a month after its release. [Van Howe 2011] Policies that apply to female genital should also apply to male genitals. At their foundation, the arguments for genital cutting of infants and children are based on cultural/ ethical relativism that includes an element of cognitive relativism, in which facts are interpreted differently to conform to cultural mandates.[Macklin 1999]

Statement 34: "It is reasonable to take these nonmedical benefits and harms for an individual into consideration when making a decision about circumcision.[13]"

Comment: **Unsubstantiated**. Reference 13 was authored by a Task Force member, and there is considerable disagreement and debate on this point.[Rawls 2001, Svaboda, Van Howe & Dwyer 2000, Dwyer 1994, Dwyer 2011] The best argument against Diekema's position is medical decisions that cannot be safely delayed should be made without delay. Decisions based on non-medical factors should be delayed until the person is able to make the decision of their own volition. By imposing one's beliefs through amputation of a body part on an incompetent infant is to treat the infant instrumentally, as though he is chattel and not a person. Questions of religion and belief should not be imposed on people, but rather chosen freely by that person.

<u>Update</u>: This issue has subsequently been addressed in detail by Darby [2013].

Statement 35: "In cases such as the decision to perform a circumcision in the newborn period (where there is reasonable disagreement about the balance between medical benefits and harms, where there are nonmedical benefits and harms that can result from a decision on whether to perform the procedure, and where the procedure is not essential to the child's immediate well-being), the parents should determine what is in the best interest of the child."

Comment: **Unsubstantiated, inconsistent with other AAP policy**. On what basis should the parents be given the authority to make this decision? See Statement 14. Parental rights are a dead dogma.[Van Howe (JME) 2013] No one has the right to determine the life of another. Slavery has been abolished. Instead, parents have a duty to protect the rights of their child.[Dwyer 1994, Dwyer 2006] Circumcision, it can easily be argued, is a human rights violation.[Royal Dutch Medical Association, 2010, Svoboda 2013]

Statement 36: "In the pluralistic society of the United States, where parents are afforded wide authority for determining what constitutes appropriate child-rearing and child welfare, it is legitimate for the parents to take into account their own cultural, religious, and ethnic traditions, in addition to medical factors, when making this choice.[11]"

Comment: **Unsubstantiated, inconsistent with other AAP policy**. See Statement 33. The question is whether the physician needs to take these factors into account. If a physician performs a circumcision for cultural, religious, or ethnic traditions, then the procedure is not within the scope of medicine, which is aimed at treating disease and deformity. If it is not within the scope of medicine, then any harms or complications from the procedure should not be covered by the physician's malpractice carrier because the procedure is not medical, but rather cultural/religious. If the AAP is going to beg third-party payers to reimburse physicians for performing the procedure for cultural/religious reasons, then they should also acknowledge that medical malpractice insurance should not be expected to provide coverage for the procedure. Since when are physicians 'cultural brokers'?

Statement 37: "Physicians who counsel families about this decision should assist parents by objectively explaining the potential benefits and risks of circumcising their infant.[10]"

Comment: Accurate, Inappropriate citation. Reference 10 does not support this statement. Instead citations about informed consent would be appropriate.[Etchells et al 1996a, Etchells et al 1996b] How can physicians provide *objective* counseling when the AAP policy statement is *not* objective? Objective counseling is not possible based on the AAP policy because there is no discussion about the normal anatomy, physiology and multiple functions of the foreskin.

Statement 38: "Because some families may opt to circumcise as part of religious or traditional practice, discussion should also encompass risks and benefits of having a medical professional

perform this procedure in a clinical setting versus having it performed by a traditional/religious provider in a nonmedical environment."

Comment: Unsubstantiated. Is there any medical study addressing this issue in detail? No. Does the AAP provide the information needed to have a full discussion of the risks and benefits? No. Since the AAP fails to address all the risks and harms involved with neonatal circumcision, it would be impossible for a medical professional relying on the contents of this report to have this discussion. Furthermore, medical providers, and of course the AAP, should denounce any surgical procedure performed by persons without a medical license. Should circumcision be performed by non-physicians, or in non-medical settings? Where is the oversight of non-medical providers? The fact that this policy statement does not categorically prohibit non-medical persons from performing a medical procedure confirms the bias of this committee and its unacceptable pandering to specific religious groups. It also sends a mixed message. If circumcision has all of the medical benefits that the Task Force feels it has, then why should nonmedically trained individuals be allowed to perform it? If non-medically trained individuals are allowed to perform circumcisions, then circumcision is more ritual than anything else. In other words, the medical excuses for circumcision provide a smokescreen for a ritual practice. Should other surgeries done outside the medical setting by non-medical persons be acceptable based on this one outlier policy by the AAP? An alternative interpretation is that the AAP motivated to protect the financial well-being of its membership that performs circumcisions by pulling business away from non-medically trained individuals.

Statement 39: "Parents may wish to consider whether the benefits of the procedure can be attained in equal measure if the procedure is delayed until the child is of sufficient age to provide his own informed consent. These interests include the medical benefits; the cultural and religious implications of being circumcised; and the fact that the procedure has the least surgical risk and the greatest accumulated health benefits if performed during the newborn period."

Comment: **Unsubstantiated, contrary to the medical literature**. No citation is given to support this statement. There is no evidence that there are accumulated health benefits, or whether these are greater with a circumcision performed earlier in life. The surgical risk has been shown to be greater with neonatal circumcision than later circumcision in one study[ref 229] and no different in another study.[ref 197] These are the only two studies that have performed a direct comparison of the same population, using the same criteria of what constituted a complication, within the same time frame. (One wonders whether the Task Force members read the publications they cited.) It has been estimated that 117 deaths occur each year in the United States as a result of infant circumcision,[Bollinger 2010] but there does not appear to be any reports of deaths in adults who are circumcised. Furthermore, research has shown that given similar noxious stimuli infants will perceive the noxious stimuli as more painful than older children and adults.[Anand & Hickey 1987] Older children and adults are far more likely to receive adequate anesthesia and post-op pain relief, more likely to be able to verbalize their pain, more likely to verbalize any discomfort or complications they may be having, and more likely to understand the surgery and give fully informed consent.

Statement 40: "Newborn males who are not circumcised at birth are much less likely to elect circumcision in adolescence or early adulthood."

Comment: Accurate. This fact is extremely important information to consider when discussing substitute judgment. When considering whether an infant would choose circumcision when competent, only about 1 in 1000 will.[Wallerstein 1980] Adolescents and adults rarely choose to be circumcised because having lived with their foreskin they know it is easy to care for and brings them pleasure. They consider the foreskin a normal and healthy body part. (If given the option of wearing a condom during intercourse or losing their foreskin, men in developed nations chose to wear a condom, which is extremely effective in preventing sexually transmitted diseases and unplanned pregnancies.)

Statement 41: "Parents who are considering deferring circumcision should be explicitly informed that circumcision performed later in life has increased risks and costs."

Comment: **Unsubstantiated, contrary to the medical literature**. No citation given. See Statement 39. Costs are increased because general anesthetic is used. The trade-off in costs is between providing adequate and inadequate anesthesia. It is also difficult to put a price tag on autonomy or on the importance of protecting a child's right to an open future with options that he can control. This statement also carries with it the unspoken, false assumption that all boys need to be circumcised, it is just a matter of when. It also implies that parents who do not circumcise their sons in infancy deserve to be "explicitly" chastised. (Of course, the AAP doesn't have to "explicitly inform" parents of the risks and harms of circumcising.)

Statement 42: "Furthermore, deferral of the procedure also requires longer healing time than if performed during the newborn period and requires sexual abstinence during healing."

Comment: **Unsubstantiated, fabricated, silly**. No citation. The Task Force made this one up. There is nothing in the medical literature that indicates any difference in healing time. The newborn also has an open wound covering all, or nearly all, of the entire surface of the glans plus a portion of the shaft may be involved, which given its surface area may take longer to heal than simple surgical excision. It is unclear how having this open wound exposed to the contents of a dirty diaper would accelerate the healing process. The removal of an infant's foreskin is a more radical procedure since the foreskin is firmly adherent to the glans. In an older child or adult, the foreskin has typically separated from the glans making the procedure less painful and less traumatic. With no studies on this topic, one can only speculate. Adult males rarely choose, or require, circumcision, so this is ridiculous. Their statement implies that circumcision will be needed as an adult, and the statement is intended to frighten, shame, guilt, or coerce parents into agreeing to neonatal circumcision.

Statement 43: "Those who are already sexually active by the time they have the procedure lose some opportunities for the protective benefit against sexually transmitted infection (STI)

Analysis of 2012 AAP Task Force on Circumcision Report

acquisition, including HIV; moreover, there is the risk of acquiring an STI if the individual is sexually active during the healing process."

Comment: **Unsubstantiated, contrary to the medical literature, fear mongering**. No citation given. Circumcision has no protective benefit against the overall risk of sexually transmitted infections, but the overall risk of STI is greater in circumcised males (discussed below).[Van Howe (STI) 2013] Both circumcised and intact men are at risk for STIs, if they do not use condoms. When sexually active, a male is competent to make the choice of how to protect himself from STIs, including condoms, which the Task Force seems afraid to mention. According to statistics from the CDC, the incidence of STIs in those too young to provide consent for circumcision (under 15 years of age) is very low. This is a common talking point used by circumcision lobbyists that is little more than fear mongering as the risks are quite low and eliminated by condom use.

Statement 44: "Finally, there is a moral obligation to take reasonable steps to reduce the risk of harm associated with the performance of any surgical intervention."

Comment: **Incomplete, ignores the obvious.** If the surgical intervention is elective and not necessary, the best way to avoid the risks associated with the surgery is to not perform it. The procedure should only be contemplated in those who can understand for themselves the risks involved, and in those who have a medical condition *requiring* treatment with this type of surgery. Infants have no medical condition *requiring* circumcision nor can they understand the risks involved.

Statement 45: "These include ensuring that the providers who perform circumcision have adequate training and demonstrate competence in performing the procedure; the provision of adequate procedural analgesia and postprocedural pain control; and that the risks of infection are minimized through appropriate infection control measures, such as a sterile environment and sterilized instruments.[14]"

Comment: **Partially accurate, unclear, and internally inconsistent**. See Statement 9. Adequate procedural and post-procedural pain is not safely available for newborns. This statement would also preclude circumcision being performed outside a medical setting by non-medical persons.

Statement 46: "The Task Force 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."

Comment: **Ironic?** The chairwoman of the Task Force was in the position to make this practice illegal in New York, yet did not take effective measures to stop the practice. Since then there have been multiple subsequent deaths from this practice. Why isn't the AAP actively voicing their concerns about this practice, which persists today in New York City?

Statement 47: "In December 2007, the AAP formed a multidisciplinary workgroup of AAP members and other stakeholders to evaluate the evidence on male circumcision and update the AAP's recommendations in this area. The Task Force included AAP representatives from specialty areas, including anesthesiology/ pain management, bioethics, child health care financing, epidemiology, fetus and newborn medicine, infectious diseases (including pediatric AIDS), and urology. The Task Force also included members of the AAP Board of Directors and liaisons representing the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and the CDC. The Task Force's evidence review was supplemented by an independent, AAP-contracted, physician and doctoral-level epidemiologist who was also part of the entire evidence review process."

Comment: Accurate (But they didn't include all the stakeholders). See Statement 4. To provide full disclosure, the circumcision status of the membership of the Task Force and whether they were circumcised or circumcised their sons should have been provided.

<u>Update</u>: An article published in October 2010 from Canada found that male physicians who were circumcised were five times more likely to recommend circumcision than other physicians and physicians who had circumcised sons were six times more likely to recommend circumcision. [Muller 2010] It is not unreasonable to think that such a bias would impact the actions of the Task Force.

Statement 48: "The Task Force members identified the following topics and questions as relevant to male circumcision and to be addressed through a critical review of the peer-reviewed literature:

What is the current epidemiology of male circumcision in the United States?

What are the most common procedures and techniques for newborn male circumcision?

What best supports the parental decision-making process regarding circumcision?

What is the association between male circumcision and both morbidity and sexual function/ satisfaction?

What is the impact of anesthesia and analgesia?

What are the common complications and the complication rates associated with male circumcision?

What workforce issues affect newborn male circumcision?

What are the trends in financing and payment for elective circumcision?"

Comment: **Biased, incomplete**. Most of these questions concern how to perpetuate the practice and how to continue receiving payment for it. They do not ask whether infant circumcision has value or whether it can be safely delayed until the male is old enough to choose for himself. They do not ask about anatomy, physiology, development, and sexual function of the foreskin. This is the real issue: what the foreskin is, what it does, how it develops, how to properly care for it, and how to maintain health and well-being of the normal penis, which will impact the health and well-being of the child and the man he will become. They do not ask about the harms (physical, psychological, sexual, societal, or ethical) associated with amputating the foreskin in an infant.

Statement 49: "The group agreed on parameters for reviewing the literature on associations between male circumcision and other outcomes. The literature review comprised analytic studies (including meta-analyses) in the topic areas in English-language, peer-reviewed, scientific literature. The Task Force evaluated studies that addressed the identified clinical questions, including all meta-analyses; all randomized controlled trials; and all case-control, prospective and retrospective cohort, and cross-sectional studies based on the American Heart Association's template for evidence evaluation (see the following section). Case reports, case series, ecological studies, reviews, and opinions were excluded from the review. Although case reports and case series are important for generating hypotheses, the Task Force limited itself to reviewing analytic studies. The Task Force compiled and vetted Medical Subject Headings, which are defined by the National Library of Medicine."

Comment: Accurate, but conducive to bias. Most complications are reported in case reports and case series. By not considering case reports and case series in their analysis, they would not be exposed to the array of complications that can follow circumcision. Consequently, their conclusion that the benefits outweighed the risks might have been influenced by the fact they were systematically excluded from considering the risks.

<u>Update</u>: In a subsequent response to critics of their report, the Task Force noted that the "benefits were felt to outweigh the risks of the procedure."[AAP Task Force 2013] (emphasis mine) Perhaps the feelings of the Task Force members would have been impacted by exposure to the many crippling complications that follow circumcision including death (Also, their review was anything but exhaustive and complete.)

Statement 50: "Searches were conducted in Medline, Cochrane Database, and Embase for the period 1995 through 2010."

Comment: **Incomplete**. The report was released in September 2012, what about all the newer studies? Plus, there are older studies that are important to the topic that were excluded from consideration.

Statement 51: "The literature search produced 1388 abstracts that were reviewed by both the epidemiologist and the Task Force chair, and those citations meeting the established criteria were included; ultimately, 1014 articles were included in the review (Table 2). A second search was

Analysis of 2012 AAP Task Force on Circumcision Report

conducted in April 2010, which yielded 42 additional citations, of which 17 were included. All 1031 accepted articles were reviewed by the contracted physician epidemiologist and at least 1 Task Force member; any differences were resolved by consensus. In 2011, individual Task Force members also identified other key articles that appeared in the peer-reviewed literature; these articles were consulted in the preparation of the current report and cited accordingly."

Comment: Accurate, but conducive to bias. If the screening of articles was limited to two persons, the conclusions reached by the Task Force could be markedly influenced by any bias present in these two individuals. For example, the Task Force chair is known to belong to an ethnic group and married within a religion that "requires" infant male circumcision. This raises a flag for a potential bias. If this was a legal proceeding, the Task Force chair would need to have recused herself based on the appearance of a conflict of interest. The identity of the epidemiologist is not provided. To avoid accusations of bias, the Task Force should have distributed this task among people without a perceived bias, and they should have devised a system in which consensus determined the inclusion or exclusion of studies. The other question is whether there was bias in the selections of the studies included for evaluation. Of the 110 citations for which a quality designation was given in the text of the report, none were "excellent," 31 were "good," 9 were "good to fair," 69 were "fair," and one was "poor." When the citations are broken down as to whether the study was supportive of male circumcision, nonsupportive of male circumcision, or neutral, pro-circumcision studies were 23 "good," four "good to fair," and 36 "fair." Of the neutral studies they were nine "good," five "good to fair," and 14 "fair." Of the 24 studies that did not support circumcision, three were "good," one "good to fair," 19 "fair", and one "poor." The Task Force clearly felt the studies that supported circumcision were on average of much higher quality than the studies that did not support circumcision. There are two possible explanations for this. One is that studies of higher quality tend to favor circumcision. The second is that studies favoring circumcision were rated as being of higher quality by the members of the Task Force not because of the quality of the study as much as because of the results of the study. Or, high-quality studies questioning circumcision were excluded by the Task Force chair before consideration by the rest of the Task Force. It is not clear whether the Task Force preferentially overlooked and disregarded a substantial body of evidence that contradicts their preformed conclusions and biases, or if their search methods were inadequate for the task. Either way, the Task Force report is not evidence-based because much of the available evidence was not considered.

Statement 52: "These additional articles did not affect the findings of the Task Force. Areas in which there were no analytic studies available for the time period of interest are noted as such within this document."

Comment: **Incomplete**. This provokes the question, what would it take to change the predetermined findings of the Task Force?

Statement 53: "Articles were reviewed by using the American Heart Association's template for evidence evaluation.[15] The articles were also assigned a level of evidence (Table 3) based on the methodology used."

Comment: Accurate, but not the standard of care as determined by the AAP and others. In 2004, the American Academy of Pediatrics Steering Committee on Quality Improvement and Management published their recommendations for classifying clinical practice guidelines.[AAP Steering Committee 2004] These guidelines follow the quality of evidence standards established by the Oxford Centre for Evidence-Based Medicine. The 2004 Academy guidelines have been routinely used in policy statements released by the Academy and were used in their 2013 statements on acute bacterial sinusitis and otitis media, as well as their 2011 statement on urinary tract infections.[Wald et al 2013, Lieberthal et al 2013, Subcommittee on Urinary Tract infection 2011] In each of these meticulous reports, the quality of evidence behind their conclusions is explicitly given. The Academy's 2012 Task Force did not use the Academy's classification recommendations. Instead, they used the American Heart Association's template for evidence evaluation, [Cummins & Hazinski 2000] which has little in common and bears no resemblance to the Academy's 2004 standard or classification system used by the Oxford Centre for Evidence-Based Medicine. It is not clear why the Task Force decided to use an unfamiliar evaluation tool and reject the Academy's established standard. As a consequence, the 2012 Task Force did not give the quality of evidence behind any of their conclusions, making it difficult to know how much weight to give to them. Finally, the template used comes from an editorial issue of a subspecialty journal, which should hardly be the basis for the standard of measuring the quality of medical evidence.

Statement 54. "Among those with evidence levels 1 through 4, the reviewers assessed the quality of the evidence as "excellent," "good," "fair," or "poor" depending on how well the methodology was applied."

Comment: **Unsubstantiated**. The quality of evidence determination criteria appear to be subjective and arbitrary. For example, "excellent" is defined as having design and methods that are "Highly appropriate sample or model, randomized, proper controls AND outstanding accuracy, precision, and data collection in its class." To their credit, the Task Force did not identify any "excellent" studies. To be a study of "good" quality, the design and methods needed to be "Highly appropriate sample or model, randomized, proper controls OR outstanding accuracy, precision, and data collection in its class." The Task Force awarded this designation freely to a variety of African randomized clinical trials. But many of these trials had serious methodological flaws that should have precluded this quality assignment. For example, the three trials that randomized men to early or late circumcision failed to collect data on the source of the infections identified during the trial, so no determination was made about where the infection came from. This lack of data collection made it impossible to accurately answer their study question.[refs 54-56] Consequently, trials with serious methodological problems cannot be classified as "good" quality. Most of the studies were categorized as "fair," which indicated that these studies had "Adequate design but possibly biased OR adequate under the circumstances."

Studies of "poor" quality were defined by "Small or clearly biased population or model OR weakly defensible in its class, limited data or measures." This should have included the African randomized clinical trials that looked at human papillomavirus by selectively sampling only the glans of the penis. [refs 71,102] Consequently, the reported results of these trials can be explained completely by sampling bias. [Storms 2009, Van Howe & Storms 2009, Van Howe 2009] So, instead of "good" quality, the built-in, easily identifiable sampling biases earn these studies a designation of "poor" quality. Finally, the Task Force did not consider studies they considered "unsatisfactory," which they defined as "Anecdotal, no controls, off target end points OR not defensible in its class, insufficient data or measures." So, the two African randomized clinical trials that looked at sexual satisfaction following circumcision, which the Task Force labeled as being of "good" quality, did not use a recognized instrument to measure their outcome. Consequently, the rates of sexual dysfunction measured in these studies were nearly non-existent and orders of magnitude lower than seen in other studies using recognized instruments. Because these studies used "insufficient" measures, they are of "unsatisfactory" quality. While these characterizations can be debated, this only underscores the subjectivity of how quality was assessed in the evidence reviewed by the AAP committee.

Statement 55: "Articles with an evidence level of 5 or higher were not included in this review. A critical assessment was made of each article/source in terms of the research design and methods, by using the American Heart Association's template (Table 4)."

Comment: **Inaccurate**. See Statement 54. As noted there, several articles that should have been properly assigned an evidence level of 5 or higher were included. It is also unclear which studies were assigned an evidence level of 5 or higher because these studies were excluded. Given the great potential for subjectivity in assigning an evidence level and the ridiculously short list of citations in the report, it is quite likely many studies were assigned an evidence level of 5 or higher that did not warrant such an assignment. The Task Force should have provided their list of rejected studies.

Statement 56: "The decision of whether to circumcise a male newborn is frequently made early in the pregnancy and even before conception.[16–18]"

Comment: Accurate. Typically the decision is not based on any accurate medical information, but on cultural or societal input.

Statement 57: "In a cross-sectional study of parents of 55 male infants presenting to a family practice clinic for a well-child visit, 80% of parents reported that the circumcision decision was made before a discussion occurred with the clinician about this issue. Only 4% of parents reportedly discussed circumcision with their clinician before the pregnancy.[16]"

Comment: Accurate.

Statement 58: "This finding is substantiated by the 2009 AAP survey of 1620 members with a response rate of 57%, in which most respondents reported that parents of newborn male patients generally do not seek their pediatrician's recommendation regarding circumcision; only 5% reported that "all" or "most" parents "are uncertain about circumcision and seek their recommendation" about the procedure.[19]"

Comment: Accurate.

Statement 59: "There is fair evidence that parental decisions about circumcision are shaped more by family and sociocultural influences than by discussion with medical clinicians or by parental education.[16,20]"

Comment: Accurate.

Statement 60: "In 4 cross-sectional studies with fair evidence, US parents most often reported that they chose to have their newborn son circumcised for health/medical benefits, including hygiene and cleanliness of the penis (reported by 39.6%, 46%, 53%, and 67%, respectively). [16,17,21,22] Social concerns (such as having a father or brother who was circumcised) were also an important reason given for newborn male circumcision (22.8%, 23.5%, 28%, and 37%). Religious requirements for circumcision, such as those of the Jewish and Islamic faiths, were ranked less high in importance (11%, 12.1%, 13%, and 19%). Although one of these studies was small and included only 55 patients drawn from a homogeneous population,[16] the findings coincide with the 3 larger and more diverse studies."

Comment: **Misleading**. While Jewish and Islamic faiths include the practice of circumcision, there are many Christians who believe that male circumcision is a religious requirement. Of the 11% to 19% who cite a religious requirement, one would expect most of these are not of the Jewish or Islamic faiths as people of these faiths are a much smaller percentage of the population in the United States (Judaism 1.9%, Muslim 0.9%).[Pew Research 2015]

Statement 61: "For parents to receive nonbiased information about male circumcision in time to inform their decisions, clinicians need to provide this information at least before conception and/ or early in the pregnancy, probably as a curriculum item in childbirth classes."

Comment: **Potentially unethical**. See Statement 12. Solicitation, or even discussion, of an unnecessary cosmetic surgery for a person who cannot consent is unethical unless the patient or parent asks for the information. The physician's obligation is to state that the surgery cannot be performed without the patient's consent.

Statement 62: "Information to assist in parental decision-making should be made available as early as possible. For this reason, obstetrician-gynecologists and family physicians who manage prenatal care probably have a more pivotal role in this decision than do pediatricians. Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition,

supports prenatal pediatric visits, at which time pediatricians can provide counseling about male circumcision (http:// brightfutures.aap.org)."

Comment: Potentially unethical. See Statement 12.

Statement 64: "There is fair evidence that there are financial barriers to the circumcision decision in the United States; when the procedure is not covered by insurance, parents are less likely to choose to have their child circumcised.[21]"

Comment: **Incomplete, biased, irrelevant**. Since this is an *elective* procedure, it does not need to be performed. The AAP policies should not be driven by financial considerations when a procedure is elective. It is the responsibility of the patient to come up with the money to pay for cosmetic procedures. Should insurance also pay for other purely cosmetic procedures: nose jobs, tattoos, piercings, breast reduction or enhancement, etc. This also strikes at the underlying motivation for this report: to increase demand and reimbursement.

Statement 65: "This finding does not seem to be true in Canada, where the prevalence of circumcision did not change after circumcision for ritual, religious, cultural, or cosmetic reasons was delisted from insurance benefits in 1994.[17,23]"

Comment: **Inappropriate citation**. Reference 23 makes no mention of Canada. The study by Walton, Ostbye, and Cambell [ref.17] measured changes in circumcision rates in the period 45 to 75 days after the procedure was delisted. This may have not been enough time from the delisting to measure an impact. Of interest, this study also found that parents with higher education levels were less likely to have their sons circumcised.

<u>Update</u>: In 2015 the Canadian Paediatric Society released its policy on circumcision, which did not reach the conclusion the 2012 AAP Task Force did.[Sorokan et al.]

Statement 66: "This review found no systematic studies in infants and children on the care of the uncircumcised versus circumcised penis."

Comment: **Incomplete**. A couple of studies were done prior to 1995.[Krueger & Osborn 1986, Osborn et al 1981]

Statement 67: "Parents of newborn boys should be instructed in the care of the penis at the time of discharge from the newborn hospital stay, regardless of whether they choose circumcision or not. The circumcised penis should be washed gently without any aggressive pulling back of the skin.[24]"

Comment: **Unsubstantiated**. Reference 24 is a pamphlet designed for parents. Of course parents should be instructed on the care of the penis; however, there is no evidence that pulling back on the skin prevents adhesions from reforming following circumcision. It may help, but it has not

been studied. Penile adhesions are a very common finding in the first year of life in circumcised boys.[ref 76]

Statement 68: "The non-circumcised penis should be washed with soap and water."

Comment: Unsubstantiated, incomplete, misleading, some medical literature to the contrary. Is the washing to take place on the inside or the outside of the foreskin? This is unclear. No citation is given. Soap is contraindicated on mucosal tissue and application to the inner surface of the foreskin has been shown to change the normal flora in an animal model to pathogenic flora.[Bowen et al 1982] The foreskin should not be retracted by anyone but its owner.[Wright 1994] Many cases of phimosis, balanitis, and nearly all cases of paraphimosis result from premature retraction of the foreskin. It is recommended that the genital mucosa of female infants be cleaned only with water. This recommendation should also apply to male genital mucosa. The "non-circumcised penis" is actually a pejorative term intended to insinuate that the normal, natural intact penis is something to be avoided. The use of "non-circumcised" has negative connotations. Other less-value-laden terms should be used instead.

Statement 69: "Most adhesions present at birth spontaneously resolve by age 2 to 4 months, and the foreskin should not be forcibly retracted."

Comment: **Contrary to the entire medical literature**. No citation given. Several studies have looked at the age at which adhesions spontaneously resolve in the intact penis. There is a range of ages when adhesions dissolve, but none of these studies found resolution by 2 to 4 months of age.[Gairdner 1949, Øster 1968, Hsu 1983, Kayaba et al 1996] The median age at which the foreskin is fully retractable is about 10 years of age.[Kayaba et al 1996] The Task Force needs to publish an errata regarding this, as a practitioner relying on this document could interpret that an infant who still has adhesions after 4 months of life has an indication for circumcision. This could result in a high number of unnecessary surgeries and attempts to prematurely forcibly retract the foreskins of infants causing extreme pain, scarring, and paraphimosis. One can only speculate that this is the goal of the Task Force, as the damage that would follow in the wake of this misstatement could be used in future pro-circumcision propaganda campaigns as a reason boys should be circumcised as infants.

Statement 70: "When these adhesions disappear physiologically (which occurs at an individual pace), the foreskin can be easily retracted, and the whole penis washed with soap and water.[25]"

Comment: **Inaccurate, unsubstantiated**. The Task Force is noticeably vague on the issues regarding normal development of the penis and resolution of foreskin attachment to the glans, as well as when the foreskin can be retracted and by whom, and/or how to care for the intact penis. Probably this is because no one on the Task Force has much experience with an intact penis, though they could have done some research into the topic or allowed persons with this knowledge a seat on the Task Force. It does not follow that the foreskin can "be easily retracted" once adhesions disappear physiologically. The size of the opening of the prepuce and the

Analysis of 2012 AAP Task Force on Circumcision Report

anatomy of the frenulum in the individual child are also factors. Reference 25 is a review article, not a scientific study. We recommend that girls do not use soap or bubble bath on their genitals because the mucosal surfaces can become irritated from these chemicals. The same applies to the mucosal surface of the male genitals. Soap should be used, if at all, only sparingly and on the epidermal surface, not the inner surface of the foreskin. This statement reinforces the suspicion that no one on the Task Force has a family member with a male foreskin. Soap can also encourage colonization with pathogenic organisms.[Bowen et al 1982] No one should retract the foreskin but the boy himself[Wright 1994] and the inner foreskin should be washed with plain water.

Statement 71: "Circumcision reduces the bacteria that accumulate under the prepuce which can cause UTIs and, in the adult male, can be a reservoir for bacteria that cause STIs."

Comment: Misleading, unsubstantiated/fabricated, contrary evidence in the medical literature. No citation is given. There are bacteria that can cause UTIs on the external genitals and periurethral region in girls. These are *normal* flora on the genitals of both intact males and intact females. These bacteria are also present in our colons. Their presence does not necessarily lead to an increase in UTIs. The foreskin actually keeps bacteria from entering the urethra because it acts as a one-way valve, which allows sterile urine out and nothing back in. Retracting the foreskin to clean under it, or removing it, does lead to changes in the bacterial flora and irritation. Both of these practices can lead to infections. We do not clean inside the vaginas of girls or recommend douching in females because of the pathologic changes in bacterial flora and irritation that results. It would have been less misleading for the Task Force to note that the normal flora in the subpreputial space consists of gram-negative organisms. There is no evidence in the medical literature that the subpreputial space is a reservoir for bacteria that cause STIs. While often repeated by circumcision proponents and lobbyists, this statement is pure fabrication. Before making this unsubstantiated statement, the Task Force should have made an effort to determine its veracity. Regarding bacterial STIs, there is no evidence that the incidence is higher in intact men. [Van Howe ISRN Urology 2013] The Task Force fails to mention that circumcised males are more likely to be colonized with gram-positive organisms and more prone to Staphylococcal infections, including MRSA infections (see Statement 72).

Statement 72: "In an internally controlled study with fair evidence, researchers cultured the periurethral and glandular sulcus of 50 children aged 1 to 12 weeks before and 4 weeks after circumcision and found the pathogenic bacteria largely disappeared after circumcision (33 children had pathogenic bacteria before circumcision and 4 had pathogenic bacteria after circumcision).[26]"

Comment: **Incomplete, misleading**. With circumcision, the gram-negative bacteria are replaced with gram-positive bacteria. This explains why MRSA infections in the newborn period affect circumcised infants 12 times more frequently.[ref 210] Other staphylococcal infections are also more likely in circumcised newborns.[Thompson et al 1966, Enzenauer et al 1985, Rush et al 1990] The pathogenicity of bacteria is often dependent on their location. *E. coli* is normal flora in

the intestine or the genital mucosa, but it is a pathogen when it is in the kidneys, bladder, or the blood. Similarly, most of the bacterial pathogens in the upper respiratory tract are normal flora in the mouth, but not when they move further into the respiratory tract. Staphylococci are normal skin flora, but they become pathogens when cultured under the skin or in the blood. Using the term "pathogenic" in the context of this statement is inappropriate and hyperbolic. It also mimics the language used by circumcision advocates and lobbyists.

Statement 73: "In adults and children, there is fair evidence that periurethral flora contains fewer pathogens after circumcision than before circumcision.[26,27]"

Comment: **Misleading, incomplete**. Normal flora includes gram-negatives and yeast. This does not mean they are pathogens, it just means that flora changes from mucosal flora to skin flora following circumcision. There is a study that found in adult males yeast was equally common in circumcised and intact men.[Davidson 1977] If these studies considered Staphylococci to be a pathogen, which they can be, then there are not fewer pathogens but only different strains of potential pathogens.

Statement 74: "Because these studies looked at cultures 1 time (4 weeks after the circumcision), the long-term significance of the findings is unclear."

Comment: Accurate. A simple explanation may be that the surgical scrub applied during the surgery altered the number and type of bacteria found.

Statement 75: "Penile wetness (defined as the observation of a diffuse homogeneous film of moisture on the surface of the glans and coronal sulcus) is considered a marker for poor penile hygiene and is more prevalent in uncircumcised than in circumcised men.[28]"

Comment: **Unsubstantiated, contrary to medical evidence**. Mucosal surfaces, such as the inside of the mouth, the inside of the eye, the vagina, the female introitus (including the labia), and the male glans and inner foreskin, are naturally moist. The authors of Reference 28 are apparently unaware of basic physiology and anatomy. If your tongue was exposed to air, it would dry out after a while. Penile wetness is a sign of normality, dryness would be an indication of pathology.

Statement 76: "Penile wetness has been associated with HIV infection in 1 cross-sectional study, although the temporal relationship is unclear and the evidence level is fair.[29]"

Comment: **Incomplete, medical evidence to the contrary**. While it is hard to see how the level of evidence is "fair", a randomized clinical trial found that waiting 10 minutes before washing after unprotected intercourse lowered the HIV infection rate in intact men compared to circumcised men.[Makumbi et al 2007] The authors of this study think there is a substance in the genital fluids which helps prevent transmission of infection.

Statement 77: "A related study with fair evidence assessed the frequency of washing the whole penis (including retracting the foreskin for uncircumcised men) and found that not always washing the whole penis was approximately 10 times more common in uncircumcised than in circumcised men.[30] The relationship between penile wetness and thorough washing of the penis is unclear and, because the studies were conducted in STI clinics, the findings may not be generalizable to the population at large."

Comment: Incomplete, medical evidence to the contrary. See Statement 76.

Statement 78: "The most notable research contributions to the literature since 1995 are studies of male circumcision and the acquisition of HIV and the transmission of other STIs."

Comment: **Hyperbole**. One could argue that the mapping of the fine-touch thresholds of the penis may be the most notable research contribution. Why they chose this area of research over other areas of research reflects the overall bias of the Task Force.

Statement 79: "Review of the literature revealed a consistently reported protective effect of 40% to 60% for male circumcision in reducing the risk of HIV acquisition among heterosexual males in areas with high HIV prevalence due to heterosexual transmission (ie, Africa)."

Comment: **Inaccurate, hyperbole**. While a few studies have reported relative risk reductions of 40%, many more studies have found no difference in HIV incidence and prevalence in circumcised and intact men. The reported results have been anything but consistent. Reporting relative risk reduction instead of absolute risk reduction can give the impression the treatment effect is more clinically important than it actually is. The treatment effect actually amounts to an absolute drop of about 1.3% in overall HIV risk reduction, *if* the studies were not flawed and biased. But, they are extremely flawed and biased with 1/2 the males who became infected not contracting HIV through sexual contact.[Boyle & Hill 2011, Van Howe & Storms 2011] Therefore, the studies are clinically meaningless. U.S. and North American studies show no relationship to circumcision status.[ref 36, ref 37, ref 135, Mor et al 2007, Thomas et al 2004, Chiasson et al 1991, Mishra et al 2009, Rodriguez-Diaz et al 2012] A recent Puerto Rican study showed increased rates of HIV, STD's and HPV of up to 10% to 30% higher in circumcised males with the prevalence of HIV significantly greater in circumcised men.[Rodriguez-Diaz et al 2012]

<u>Update</u>: An analysis published recently of 109 populations in which the incidence or prevalence of HIV infection has been compared between intact and circumcised men demonstrated that the 40% to 60% reduction has not been consistently reported, with these results representing possible outliers.[Van Howe 2015]

Statement 80: "There is also good evidence from randomized controlled trials that male circumcision is associated with a lower prevalence of human papillomavirus (HPV) infection[31,32]" ...

Analysis of 2012 AAP Task Force on Circumcision Report

Comment: Unsubstantiated, inaccurate, misleading, hyperbolic, incomplete, contradicted in the medical literature. Reference 31 is a review article/opinion piece. Reference 32 is a poorly designed study in Africa that used a collection method with only 75% sensitivity. When the two HPV strains responsible for the majority of cervical cancer cases were considered, there was no difference in women who had circumcised versus intact male partners. Meta-analyses of HPV infection in men failed to find a difference in infection rate based on circumcision status.[Van Howe J Infect 2007, Van Howe ISRN Urology 2013] Most of the studies suffered from sampling bias and misclassification bias. There was a statistically significant difference in the odds ratios reported in studies that did not completely sample the penis for HPV and that relied on patient report for circumcision status. When adjusted for the impact of these forms of bias, there was no difference in risk. [Van Howe J Infect 2007, Van Howe & Storms 2009] Two randomized trials found a higher rate of HPV in intact men, but neither study sampled the shaft of the penis, [ref 71] 102] which is where HPV is more likely to be found in circumcised males.[Weaver 2004, VanBuskirk et al 2011] If the penile shaft is not sampled, the rate of HPV infections in circumcised males will be underestimated by 30% to 35%. [Weaver 2004, VanBuskirk et al 2011] Consequently, the differences seen in the two randomized trials can be completely attributed to sampling bias.[Storms 2009, Van Howe 2009] In a study of women attending the University of Washington, no difference was found in HPV rates based on the circumcision status of the male sexual partner.[Winer et al 2003] Similarly, no association was found in men attending the University of Washington between HPV infection and circumcision status. [VanBuskirk et al 2011] So much for "good" evidence.

<u>Update</u>: A subsequent meta-analysis found that neither the incidence nor the prevalence of genital HPV (especially those strains known to be oncogenic) were significantly associated with circumcision status. [Van Howe (STI) 2013] More notably, the HPV Infections in Men (HIM) study, the largest prospective study of genital HPV incidence in men published to date (4,033 men), found that the incidence of HPV, either oncogenic or non-oncogenic, was similar in intact and circumcised men, but that oncogenic HPV strains were eradicated from the penis significantly more quickly in intact men.[Albero et al 2014]

Statement 81: "... and herpes simplex virus type 2 (HSV-2) transmission, [31,33] ..."

Comment: Unsubstantiated, inaccurate, misleading, hyperbolic, incomplete, contradicted in the medical literature. Reference 31 is a review article/opinion piece. Discussed in detail below (Statements 119-125).

Statement 82: "... as well as a decreased likelihood of bacterial vaginosis (BV) in female partners.[80]"

Comment: Unsubstantiated, inaccurate, misleading, hyperbolic, incomplete, contradicted in the medical literature. Reference 80 is a review article/opinion piece. See Statement 137 for further discussion.

Statement 83: "The evidence for male circumcision being protective against syphilis is less strong,[65–68] however, and male circumcision was not found to be associated with decreased risk of gonorrhea[84,85,91–93] or chlamydia.[84–89]"

Comment: **Incomplete, superficially researched**. Reference 67 is a review article/opinion piece. These topics are discussed individually below.

Statement 84: "It is biologically plausible that the circumcised state may confer protection against STIs (including HIV). Possible mechanisms for the protective effect of circumcision include the fact that the foreskin's thin inner surface is susceptible to microtears and abrasions (especially during sexual activity), which provides a port of entry for pathogens."

Comment: Unsubstantiated/fabricated, contradicted in the medical literature. No citation provided. Such "microtears" and abrasions are a speculative work of fiction. This myth has been repeated so many times that many now believe it is true. Only one study has looked at the risk of penile abrasions. It found that intact men were less likely to have penile abrasions, but the difference was not statistically significant (OR=0.80, 95%CI=0.50-1.28).[Bailey et al 1999] Histological evidence has shown that the thickness of the epithelial layer of the glans, the inner foreskin, and the outer foreskin is the same.[Dinh et al 2010, Dinh et al 2012]

Statement 85: "The foreskin also contains a high density of HIV target cells (ie, Langerhans cells, CD4 T cells, macrophages), which facilitates HIV infection of host cells. The preputial space provides an environment that is thought to "trap" pathogens and bodily secretions and favor their survival and replication.[26,27,34]"

Comment: **Unsubstantiated, misleading, improper citation, contrary to medical evidence**. There are immunogenic cells on all of our skin and mucosal surfaces. Their role in facilitating HIV infection is still speculative. While there are receptor sites for HIV on these cells in *in vitro* studies, *in vivo* evidence is lacking. The concentration of these cells is the same on the glans and the inner foreskin. The rate of sexual transmission of HIV through coitus is approximately 1 in 1000,[Chin 2007] so the mucosal immunity is quite effective and the HIV target cells, along with a secreted substance called langerin are doing their job. It is only when viral counts are high that the protective cells are overwhelmed.[de Witte et al 2007] References 26, 27, and 34 do not provide any scientific evidence to support this claim, but merely speculation of what is stated here. This is a common talking point, with no supportive evidence, often used by circumcision advocates and lobbyists. The facts are that the "HIV target cells" serve to prevent HIV infection, not facilitate it. Before making this unsubstantiated statement the Task Force should have made an effort to determine its veracity.

Statement 86: "The circumcised male has no foreskin and may likely provide a less welcoming environment for such substances."

Comment: **Unsubstantiated/fabrication, medical evidence to the contrary**. No citation is given. This is pure speculation. Not all of the foreskin is typically removed during circumcision. The amount of foreskin remaining following circumcision can be quite variable.[ref 76] To state the "circumcised male has no foreskin" reflects the lack of expertise by the Task Force members in this area.

Statement 87: "In addition, STI-containing secretions have increased contact time in the prospective uncircumcised male host, which may increase the likelihood of transmission and infection."

Comment: Unsubstantiated/fabrication, medical evidence to the contrary: No citation given. This is pure speculation.

<u>Update</u>: The HIM study of genital HPV infections in men found that HPV is cleared more quickly in intact men than in circumcised men because there is less contact time.[Albero et al 2014]

Statement 88: "The exposed surfaces of the uncircumcised penis do not offer the same physical barrier to resist infection that the highly keratinized surface of a circumcised penis does."

Comment: Unsubstantiated/fabrication, inconsistent, medical evidence to contrary: No citation given. This is pure speculation. If the surface is highly keratinized, then that might help explain why the glans of the circumcised penis is less sensitive to fine touch than the normal penis.[ref 128, 132] One opinion piece made mention of seven circumcised males and six normal males where the epithelia was found to be equally keratinized. Further details were not provided. [Szabo & Short 2000] As mentioned in Statement 84, histological evidence has shown that the thickness of the epithelial layer of the glans, the inner foreskin, and the outer foreskin is the same,[Dinh et al 2010, Dinh et al 2012] so the physical barrier is the same.

Statement 89: "Finally, the higher rates of sexually transmitted genital ulcerative disease (eg, HSV-2) observed in uncircumcised men may also increase susceptibility to HIV infection, as the presence of genital ulcers, irrespective of circumcision status, increases the likelihood of HIV acquisition.[35–37]"

Comment: Accurate, but incomplete. Reference 35 is a review article/opinion piece. The association between the risk of STIs and HIV infection may be that being diagnosed with an STI is a marker of having unprotected sex with potentially infected partners. The link to genital ulcerative disease may be related to breaks in mucosal integrity at ulcer sites and the presence of T-cells that are activated by the infectious cause of the ulcer. On the other hand, those diagnosed with STIs are more likely to receive treatment. In Africa, this can often be in the form of injections given through contaminated needles. Medical care and proximity to clinics are independent risk factors for HIV infection in Africa. As discussed in Statements 119 to 125.

<u>Update</u>: The spread of HIV through contaminated needles was acknowledged in 2015 by the highly regarded AIDS researcher Peter Piot.[Piot 2015]

Statement 90: "The CDC estimates that 1.2 million people in the United States are living with HIV, the virus that causes AIDS, which is incurable. Approximately 50 000 Americans are newly infected with HIV each year; more than 619 000 people in the United States have died of AIDS since the epidemic began.[38] In the United States, HIV/AIDS predominantly affects men who have sex with men (MSM), who account for almost two-thirds (61%) of all new infections. Heterosexual exposure accounts for 27% of new HIV infections, and injection drug use accounts for 9% of new HIV cases."

Comment: Accurate, but outdated.

<u>Update</u>: HIV is now considered a chronic disease rather than a fatal disease. Evidence also indicates that the virus is losing its virulence. [Payne et al 2014] It is important to note that circumcision does not affect the incidence or prevalence of HIV in MSM. [ref 61, Crosby et al 2015]

Statement 91: "In other parts of the world (eg, Africa), heterosexual transmission is far more common.[39]"

Comment: **Unsubstantiated, contrary to medical evidence**. The basic epidemiology of the source of HIV infections has not been studied, so it has not been documented whether heterosexual transmission is far more common. Part of the problem in Africa is that homosexuality is a capital offense, so those who engage in these practices are unlikely to be forthcoming, even in a research setting. Evidence is also growing that a substantial portion of HIV infections are from non-sexual means, such as tattoos, scarification, and medical injections. [Gisselquist et al 2002, Gisselquist & Potterat 2003, Gisselquist et al 2003, Brewer et al 2003, Gisselquist et al 2004, Gisselquist 2008a, Gisselquist 2008b, Ounga et al 2009, Gisselquist 2009a, Gisselquist 2009b, Gisselquist et al 2009, Piot 2015] The statement above also has nothing to do with HIV in the US except to use the flawed studies as "proof" that circumcision is effective against heterosexually-transmitted HIV.

Statement 92: "Fourteen studies provide fair evidence that circumcision is protective against heterosexually acquired HIV infection in men.[40–53]"

Comment: **Incomplete/Misleading/Hyperbole**. The list of studies excluded that show the opposite result is three times longer than the ones included. A search of the medical literature in November 2012 was able to identify 109 populations that evaluated the risk of heterosexually acquired HIV in men based on their circumcision status. [ref 36, ref 37, ref 42, ref 43, ref 44, ref 46, ref 47, ref 49, ref 50, ref 51, ref 52, ref 53, ref 54, ref 55, ref 56, ref 57, ref 59, ref 86, ref 93, ref 94, ref 135, Agot et al 2004, Allain et al 2004, Auvert et al 2001, Barongo et al 1992, Barring et al 1994, Bloom et al 2002, Bollinger et al 1997, Bwayo et al 1991, Bwayo et al 1994,

Cameron et al 1989, Carael et al 1988, Chiasson et al 1991, Dandona et al 2008, Demographic and Health Surveys (Rwanda) 2006, Diallo et al 1992, Diallo et al 2008, Foglia et al 2008, Gilks et al 1992, Gomo et al 1997, Greenblatt et al 1988, Hargreaves 2002, Harrison et al 1991, Haffron et al 2011, Hira et al 1990, Hugonnet et al 2002, Kapiga et al 2006, Kisesa 1996, Kumwenda et al 2001, Lankoande et al 1998, MacDonald et al 2001, Malawi National Statistical Office 2011, Mehendale et al 1996, Mermin et al 2008, Mishra et al 2009, Mor et al 2007, Nasio et al 1996, Pedhambkar et al 2001, Pison et al 1993, Quigley et al 1997, Quinn et al 2000, Rakwar et al 1999, Rodrigues et al 1995, Sassan Mororkro et al 1996, Serwadda et al 1992, Simonsen et al 1988, Thomas et al 2004, Tyndall et al 1996, Van de Perre et al 1987, Vaz et al 1995, Wawer et al 1999] The Task Force only considered 12.8% of the studies available. More importantly, North American studies do not show that circumcision is protective against HIV. [ref 36, ref 37, ref 135, Mor et al 2007, Thomas et al 2004, Chiasson et al 1991, Mishra et al 2009, Rodriguez-Diaz et al 2012]

Statement 93: "One study with fair evidence found that male circumcision before puberty (specifically before 12 years of age) is more protective than circumcision occurring at a later age. [50]"

Comment: **Incomplete, misleading.** There are also studies which show the opposite results. For example, one study found that circumcisions performed after age 15 years was associated with a decreased risk of HIV infection (OR=0.48, 95%CI=0.25–0.90).[Quigley et al 1997] (This is one of many examples of studies published after 1995 that should have been included in the Task Force's literature search and policy statement. One can only speculate whether these studies were ignored or just not found.) It appears that the Task Force is trying to make the case for infant circumcision rather than later circumcision, or no circumcision at all. It bears repeating that the trials in Africa were *not* on infants but on supposedly "consenting" *adults*.

Statement 94: "Three large randomized controlled trials provide good evidence of such protection.[54–56]"

Comment: **Misleading/Inaccurate**. The evidence in the large randomized clinical trials is not as good as the Task Force defines it ("Highly appropriate sample or model, randomized, proper controls OR outstanding accuracy, precision, and data collection in its class"). All three trials had nearly identical methodology, which was markedly flawed. Forms of built-in bias, all of which would overestimate the treatment effect, include selection bias, expectation bias (both for participants and researchers), lead-time bias, geographic bias, attrition bias, duration bias, and early termination (which also amplified the lead-time bias). The attrition bias is particularly concerning in that for every man who had an HIV-infection detected during the course of the trial, between three and seven study participants were lost to follow-up. The small absolute risk reduction (1.3%) could easily be explained from the cumulative effects of the various forms of bias. More importantly, based on the data provided in these trials, approximately half of the men who became infected during the trial were infected through non-sexual transmission. None of the trials made an attempt to determine the source of the infections that occurred during the trials.

[Green et al. 2008, Green et al 2010, Boyle & Hill 2011, Van Howe & Storms 2011 (HIV)] Based on this, these trials should have been rated as "poor" because the failure to assess the source of infections would be needed to be "adequate under the circumstances" — the threshold for a "fair" rating. The Centre for Evidence-Based Medicine uses a different grading system for published studies. They have a category for low quality randomized trials (poor design and lack of follow-up) that would apply to these trials (category 2b), which are lower in quality than welldesigned cross-sectional studies. There have also been ethical issues raised concerning these trials.[Siegfried 2005, Cleaton-Jones 2005, Van Howe, Svoboda & Hodges 2005] Rating these trials as "good evidence" indicates bias on the part of the Task Force. The strong, unquestioning reliance on the findings of these trials by the Task Force is consistent with the position taken by circumcision advocates and lobbyists.

<u>Update</u>: The CDC's draft recommendation also placed too much emphasis on the results of these "poor" quality studies.[CDC 2014]

Statement 95: "A cross-sectional study with fair evidence is neutral regarding the relationship between circumcision and HIV infection.[57]"

Comment: **Incomplete**. See Statement 92. There are multiple national cross-sectional surveys that found either neutral results or a higher prevalence of HIV in circumcised men that the Task Force either failed to find or ignored.[Mishra et al 2009, Garenne 2008, Demographic and Health Surveys (Rwanda) 2006, Malawi National Statistical Office 2011]

<u>Update</u>: In 2013 Garner and colleagues noted that national surveys prior to the initiation of the randomized clinical trials indicated that, even if these trials demonstrated a treatment effect in a research setting, the results would not translate to the general public. As a consequence, the trials were unnecessary and, as some argued, unethical.[Garenne et al 2013,Van Howe, Svoboda, Hodges 2004]

Statement 96: "Two other studies with a cross-sectional design provide fair evidence that circumcision increases the risk of HIV infection, although one of these studies highlights the HIV risks associated with circumcision performed outside the hospital setting and without sterile equipment and medically trained personnel.[58,59]"

Comment: **Incomplete, inaccurate**. See Statement 92. It is not clear which study the Task Force is referring to when indicating that the circumcisions were performed outside the hospital setting. Both studies looked at populations in which most of the circumcisions would be performed outside the hospital setting, so it is not clear why they singled out one study, which they fail to identify.

Statement 97: "A recently published study from the CDC provides good evidence that, in the United States, male circumcision before the age of sexual debut would reduce HIV acquisition among heterosexual males.[60]"

Comment: **Misleading/Inaccurate**. It is hard to classify this publication as a "study" because it is actually a modeling exercise. It is also hard to classify it as "good evidence" when the model's assumptions are based on studies with fair and poor evidence. At the very best, it would rank as "fair," since it has a clear bias by making assumptions that are based on questionable studies from other continents.[Van Howe 2010, Anderson 2010] The effectiveness of circumcision was assumed to be 60% in the United States, despite the fact that not a single study in North America has found a significant association between circumcision status and heterosexual HIV incidence or prevalence.[ref 36, 135, Mor et al 2007, Thomas et al 2004, Mishra et al (Haitian data) 2009, Chiasson et al 1991] A recent study from Puerto Rico found that circumcised men were at significantly increased risk for HIV infection.[Rodriguez-Diaz et al 2012]

Statement 98: "Although individual sexual practices are difficult to predict in the newborn period, the majority of US males are heterosexual and could benefit from male circumcision."

Comment: **Unsubstantiated, inconsistent with medical evidence, pure speculation, hyperbole.** No studies in North America have shown a benefit for heterosexual males. [ref 36, 135, Mor et al 2007, Thomas et al 2004, Mishra et al (Haitian data) 2009, Chiasson et al 1991] One Puerto Rican study found circumcised men to be at statistically greater risk for HIV infection (intact versus circumcised OR=0.68, 95%CI=0.49-0.95).[Rodriguez-Diaz et al 2012] The concept of heterosexual men in the United States benefiting from male circumcision is based on beliefs and hopes, not scientific evidence. This statement could easily be misinterpreted. Saying that the majority of males in the US *could* benefit from male circumcision is hyperbolic without an accompanying disclaimer that very few (less than 2%), if any, US males *will* benefit from male circumcision. It is also impossible to identify the few, if any, males that did benefit. The statement gives the impression that the benefits are common, when they are not.

Statement 99: "Mathematical modeling by the CDC shows that, taking an average efficacy of 60% from the African trials, and assuming the protective effect of circumcision applies only to heterosexually acquired HIV, there would be a 15.7% reduction in lifetime HIV risk for all males. This is taking into account the proportion of HIV that is acquired through heterosexual sex and reducing that by 60%. The percent reduction in HIV cases was determined by assessing the proportion of new cases of HIV infection that could be prevented by analyzing which infections would be presumed to occur in uncircumcised males and what the reduction would be if those who would not already be circumcised would be circumcised."

Comment: **Unsubstantiated, misleading, incomplete**. See Statement 97. The model is based on assumptions that have no basis in reality, so it produced an unrealistic result. The Task Force fails to mention that the model determined that circumcision, using their assumptions, was only cost-effective for blacks and Hispanics, but not cost-effective for Caucasians. So, if the results of this analysis are as "good" as the Task Force believes it is, they should amend their statement to state that the benefits outweigh the risks only for blacks and Hispanics, but not for Caucasians. How this applies to children of mixed heritage is anyone's guess. Following this logic, circumcision

should only be offered to Blacks and Hispanics, which would give the message that these racial and ethnic groups are promiscuous and lack the wherewithal to use condoms. The underlying message could be interpreted as racist and anti-immigrant.

Statement 100: "The proportions of transmissions prevented are lower than in Africa because a higher proportion of US HIV transmission occurs between MSM."

Comment: Misleading, inconsistent with epidemiological evidence, unclear. See Statement 97. There is no evidence that circumcision is associated with a lower incidence or prevalence of HIV in North America, so the number of transmissions prevented would be lower, since circumcision has not been shown to prevent transmission in North America. It also has not been shown to prevent HIV transmission in Africa. In national surveillance data collected in 16 African countries, HIV prevalence was greater among circumcised men in eight of them. These countries included Burkina Faso, Cameroon, Lesotho, Malawi, Niger, Rwanda, South Africa, Tanzania, and Zimbabwe.[ref 57, Mishra et al 2009] When these data are combined using a randoms-effects model, no statistically significant difference can be found in HIV prevalence (intact versus circumcised, summary OR=1.10, 95%CI=0.81-1.50, between-study heterogeneity chi-square (df=15)=107.22, p<.0001).[Van Howe & Storms 2011] It is unclear what the Task Force means by "proportions of transmissions." Are they referring to *relative* risk reductions, which the model assumed (erroneously) were the same in the US and Africa, or the *absolute* risk reduction, which would be lower than in Africa because the incidence of HIV is greater in Africa? Are they assuming the transmission rate between MSM is lower in Africa? Not much evidence to support this assumption as this rate has not been determined given the penalties there for MSM activities

Statement 101: "In addition, a portion of the population would be circumcised without any policy change, and the prevented cases would only occur in the additional circumcised males. This ranges from an estimated 8% reduction in non-Hispanic white males to an estimated 21% reduction among non-Hispanic black males."

Comment: **Unsubstantiated**. See Statements 97 and 100. There is no evidence that circumcision is associated with a lower incidence or prevalence of HIV in North America. These numbers are not from an actual "study" but from a model based on erroneous assumptions.

Statement 102: "The CDC study suggests that newborn circumcision performed in the United States to prevent HIV infection is cost-effective without consideration of other health benefits. The CDC recommendations state that all parents of newborn males should be given the choice of circumcision."

Comment: **Unsubstantiated**. See Statements 97 and 100. These numbers are not from an actual "study" but from a model based on erroneous assumptions. There is no evidence that circumcision is associated with a lower incidence or prevalence of HIV in North America.

Likewise, "other health benefits" have not been clearly documented. The model assumed that the procedure had no complications. Harms must be taken into account in any cost-analysis.

Statement 103: "The association of circumcision and the decreased likelihood of HIV acquisition applies to heterosexual males."

Comment: **Unsubstantiated**. As discussed earlier, the studies that have suggested this have serious problems with internal and external validity. The inconsistency of findings make this claim impossible to make, especially in North America, where none of the studies performed here support this claim.

<u>Update</u>: Estimates from a meta-regression model based on 109 populations of men, indicate that circumcision would not be effective in the United States.[Van Howe 2015]

Statement 104: "Circumcision seems to be less likely to protect MSM, however, and has not been associated with decreased acquisition of HIV among MSM.[61]"

Comment: **Misleading, incomplete**. The language "seems to be less likely to protect" is too soft. The meta-analysis found no difference. The Task Force also needs to include reference to the long errata that was published after the initial publication of this meta-analysis. The original publication, while it found no statistically significant difference, miscalculated the summary effect. When calculated properly, the summary effect was reduced from a non-significant trend with 14% protection to a weaker trend with only 5% protection.[Errata JAMA 2009; 301: 1126-9] Other studies have been published since the publication of this meta-analysis. Studies from London, Australia, Peru and the United States failed to find a difference.[Thornton et al 2011, Templeton et al 2009, Jozkowski et al 2010, Gust et al 2010, Jameson et al 2009, Sanchez et al 2009, Crosby et al 2015] One study of Latin American immigrants to the United States found a positive association between intact men and HIV, but only among those from Columbia, and not those from Brazil or the Dominican Republic.[Reisen et al 2008]

Modeling of the impact of circumcision on HIV infections in MSM indicates that the procedure will not produce a substantial decrease in HIV prevalence or incidence in this population. [Londish et al 2010] Another model found that, for the resources used, other interventions were more effective.[Anderson et al 2009] Such inconsistencies in HIV protection suggest problems with the hypothesis that circumcision impacts the risk of HIV infection. The question is how many negative studies will it take before the CDC decides enough is enough?

<u>Update</u>: A model published by the CDC found that circumcision had essentially no role in HIV prevention in discordant MSM couples.[Lasry et al 2014]

Statement 105: "There is fair evidence from 1 study that there is a protective effect of circumcision from HIV infection in MSM; however, this study used self-report to establish circumcision status.[62]"

Comment: **Misleading**. If the study relied on self-report, how can it not be a study with "poor" evidence? Why did the Task Force single out this study and fail to mention all the other negative studies?

Statement 106: "One study with fair evidence is neutral regarding the relationship between circumcision and HIV infection in MSM.[61]"

Comment: **Unclear, inappropriate citation**. Reference 61 is a meta-analysis, not a "study." It is unclear why the Task Force would mention a single study (among others) with a positive association (Reference 62) when there are other positive studies, and they fail to mention the many studies that have failed to find an association (see studies included in Reference 61). This is another example of how lax the Task Force was in exploring the medical literature.

Statement 107: "It is probable that the differences found in the level of protection (or lack of protection) by studies of MSM are confounded by the fact that MSM commonly perform both receptive and insertive sex. It is not known to what extent circumcision may be protective against HIV transmission for MSM who practice insertive sex versus for those who engage in receptive sex."

Comment: **Misleading, biased, incomplete**. The Task Force appears to be convinced circumcision will decrease the risk of HIV in MSM, but apparently they believe the right studies haven't been done yet to find the evidence. They need to look objectively at what the evidence tells them rather than trying to twist the data to suit their pro-circumcision agenda. Studies have looked specifically at insertive versus receptive sex. Two abstracts found a slight increase in risk for insertive sex in MSM with an intact penis.[Sanchez 2007, Templeton et al 2008] Other studies have found no difference for those practicing unprotected insertive sex.[Gust et al 2010, Jameson et al 2009] The expectation bias on the part of the Task Force is unprofessional and inappropriate for a supposedly scientific organization.

Statement 108: "Women account for 23% of new HIV infections in the United States; HIV infection in women is primarily attributed either to heterosexual contact or injection drug use. [38]"

Comment: Accurate.

Statement 109: "Two prospective cohort studies with fair evidence looked at the relationship between a woman's risk of HIV infection and whether her primary male partner is circumcised. The first study describes a protective effect but had considerable loss-to-follow-up and possible misclassification of the partners' circumcision status.[63]"

Comment: **Misleading**. This study had only 22 women who had husbands with an intact penis and only three of these became HIV-infected. The lower 95% confidence interval was 1.0009

while the Fisher exact-test p value was 0.0722, indicating that the association was not statistically significant. The Task Force failed to identify this as a "poor" study. This study did not attempt to identify the source of HIV infection.

Statement 110: "The other study showed nonsignificant protection in the high-risk group (ie, women who were more likely to have ever engaged in sex work; to have reported 2 or more partners in the last 3 months; and/or to have had a higher median lifetime number of sex partners) but neither protection nor increased risk in the study population as a whole.[64]"

Comment: Accurate. This study did not attempt to identify the source of HIV infection.

Statement 111: "A meta-analysis with good evidence of data from 1 randomized controlled trial (RCT) and 6 longitudinal analyses found little evidence that male circumcision directly reduces their female partner's risk of acquiring HIV (summary relative risk: 0.8 [95% confidence interval (CI): 0.53–1.36]); however, male circumcision's protective effect did not reach a level of statistical significance.[65]"

Comment: **Incomplete, confusing**. The meta-analysis included a randomized clinical trial that was halted early as the intervention (circumcising HIV-positive men) was determined to increase the risk of HIV infection in their female sexual partners.[ref 66] Because of ethical considerations, the trial was stopped appropriately. Consequently, the summary effect calculated in the meta-analysis would overestimate the treatment effect of circumcision, and underestimate the harm of circumcision. The statement regarding statistical significance is unnecessary and reflects a confirmation bias (the assumption being that circumcision is protective, but statistical significance has not yet been achieved).

Statement 112: "One Ugandan RCT study with good evidence found that, at 24 months, the risk of HIV infection among women whose male partners were circumcised was 21.7% compared with 13.4% for female partners of uncircumcised men.[66]"

Comment: **Incomplete**. This study was halted, appropriately so, before the number of HIV infections in the female partners of HIV-infected men who were randomized to early circumcision could provide enough statistical power to yield a statistically significant difference if one existed. The authors of this study have spun the results of this trial as having found no significant increased HIV risk for the female partners. The data safety review board could not, in good conscience, allow the study to continue until the difference became statistically significant. The authors of the trial concluded that even though there was an increased risk of HIV infection in the female partners of HIV-infected men who get circumcised, HIV-infected men should still be circumcised to avoid any stigmatization associated with having an intact penis. The ethics of this trial, in which both male and female participants were not routinely informed of the HIV status of the male participants, have been called into question.[Okwuosa 2009, Berer 2009, Gupta & Goel 2009] The bottom line is that, in the only randomized trial completed to date, male

circumcision appears to increase the risk of HIV infection in women. Therefore, to promote circumcision as a preventive measure is dangerous.

Statement 113: "Genital ulcers are notable both because of the morbidity and mortality associated with the causative organism and because the presence of the ulcer itself facilitates the transmission of HIV."

Comment: **Incomplete**. The association between circumcision and HIV infection in Africa in high-risk populations may be completely attributed to genital ulcers. Genital ulcers present a break in the mucosa allowing HIV to be transmitted and to also activate T-cells, an important step in HIV transmission. The reason for the lack of an association between circumcision and HIV infection in North America may be the infrequency of genital ulcers.

Statement 114: "From 2009 to 2010, there were 13 604 cases of early latent syphilis reported to the CDC and 18 079 cases of late and late latent syphilis. The rate of primary and secondary syphilis in 2010 was 4.5 cases per 100 000 individuals, 2.2% lower than the 2009 rate. "The total number of cases of syphilis (primary and secondary, early latent, late, late latent, and congenital) reported to CDC increased 2.2% (from 44,830 to 45,834 cases) during 2009–2010."[67] A large percentage of syphilis cases occur in MSM; in 2010, 67% of the reported primary and secondary syphilis cases were among MSM.[67]"

Comment: Accurate.

Statement 115: "The balance of evidence suggests that male circumcision is protective against syphilis.[68–70]"

Comment: **Incomplete, inappropriate citation**. Several studies have been published since the meta-analysis. At least three studies found a non-significant trend for an increase in syphilis risk in circumcised men.[ref 71, 93, Rodriguez-Diaz 2012] One study, from a San Francisco STD clinic, found no difference in syphilis in MSM, but instead found an increase in syphilis in intact men who reported being heterosexual.[Mor et al 2007] Reference 70 did not study the incidence or prevalence of syphilis.

Statement 116: "One meta-analysis with good evidence describes a protective effect (relative risk: 0.67 [95% CI: 0.54–0.83]), but there is considerable heterogeneity among the studies included.[68]"

Comment: **Incomplete**. Because of the considerable between-study heterogeneity (inconsistency in the study results) the summary effect is suspect. The results of the meta-analysis appear to be driven by the studies of high-risk men in Africa. How this relates to low-risk men in North America is unknown.

<u>Update</u>: An updated meta-analysis found that the seroprevalence of syphilis was greater in intact men (intact versus circumcised OR=1.30, 95%CI=1.11-1.53), but found no overall difference in incidence (RR=0.87, 95%CI=0.61-1.26).[Van Howe (STI) 2013]

Statement 117: "An additional cohort study with fair evidence found that circumcised men were significantly less likely to have active syphilis at the point of study recruitment; when the men were followed up prospectively for 2 years, a protective effect was also observed but was nonsignificant.[69]"

Comment: **Accurate, incomplete**. It is unclear why the Task Force mentions this one African study from 2001, when there are plenty of other studies in their reference list that could be mentioned. [ref 47, ref 49, ref 51, ref 53, ref 86, ref 87, ref 93, ref 94, ref 135, Bailey et al 1999, Buvé et al 2001, Cook et al 1994, Dave et al 2003, Donovan eta l 1994, Hand 1949, Lloyd & Lloyd 1934, Mor et al 2007, Newell et al 1993, Otieno-Nyunya et al 2011, Parker et al 1983, Rodriguez-Diaz et al 2012, Schneider et al 2010, Schrek & Lenowitz 1947, Ministry of Health (Uganda) 2012, Vaz et al 1995, Wilson 1947] What is the importance of this study that makes it worthy of mentioning?

Statement 118: "Good evidence from a large RCT reported no reduction or trend toward reduction for male circumcision and the incidence of syphilis[71]; however, the extent to which protection might be afforded, and among which specific populations, is difficult to determine."

Comment: **Misleading**. The expression "no reduction or trend toward reduction" is quite awkward. Simply stating that there was a non-significant trend towards an increased risk in the incidence of syphilis for circumcised males would have done the trick. Such wording suggests bias on the part of the Task Force.

<u>Update</u>: A population study from India found prevalence was higher in circumcised males, but the trend was not statistically significant.[Schneider et al 2010] A more recent meta-analysis of syphilis finds that prevalence may be higher in intact men, incidence is unaffected.[Van Howe (STI) 2013] Another study from Africa found that in HIV-negative men, there was a nonsignificant trend toward fewer infections with syphilis in circumcised men.[Pintye et al 2014] When combined with other studies, the incidence is still no different based on circumcision status.

Statement 119: "Genital herpes is an STI commonly manifested by recurrent genital ulcers caused by HSV-1 or HSV-2. HSV may not be clinically evident despite infection. Approximately 16.2% of US individuals aged 14 to 49 years have HSV-2.[31,72]"

Comment: Accurate, unclear. By having HSV-2, does that mean clinically or serologically?

Statement 120: "Case reporting data for genital HSV are not available, but 2005–2008 NHANES data indicate that the percentage of NHANES participants aged 20 to 49 years who reported having been diagnosed with genital herpes at some point was 18.9%.[72]"

Comment: Accurate.

Statement 121: "One meta-analysis with good evidence found some protective effect of circumcision against HSV-2 of borderline statistical significance.[68]"

Comment: **Inaccurate, misleading, incomplete**. What is "borderline statistical significance?" Is that like "kind of pregnant?" Things are either statistically significant or they are not. The summary effect reported in Reference 68 was not statistically significant. The meta-analysis failed to include the data from two of the four geographic locations in a study in which the lead author was also the lead author of this meta-analysis. Both excluded populations showed trends towards a higher risk of HSV in circumcised males.[Weiss et al 2001] Several studies have been published since the meta-analysis. Some have failed to find a statistically significant difference. [refs 6, 73, 74, 134, Mehta 2012, Rodriguez-Diaz et al 2012, Sobngwi-Tambekou et al 2009, Ferris et al 2010] One trial found a protective effect for circumcision, but when adjusted for lead-time bias, the difference was not statistically significant.[ref 71, Storms 2009] One study found the seroprevalence to be significantly higher in circumcised males.[O Ng'ayo et al 2008] If studies that the authors knew about were excluded from the analysis, how can this be "good" evidence?

<u>Update</u>: A large population based study in India found that circumcised men had a significantly higher prevalence of HSV.[Schneider et al 2010] A more recent meta-analysis found no significant difference in HSV incidence or prevalence (intact versus circumcised: prevalence OR=1.15, 95%CI=0.95-1.40; incidence RR=1.15, 95%CI=0.97-1.36).[Van Howe (STI) 2013]

Statement 122: "Good evidence of the protective effect of male circumcision is available from two of the large randomized controlled trials in Africa. In the South African study, the incidence of HSV-2 was 34% lower in circumcised men.[73]"

Comment: **Misleading, incomplete, wrong citation**. Reference 73 does not address HSV-2 infections. The proper reference is not listed in the references.[Sobngwi-Tambekou et al 2009] The "intention to treat" analysis failed to find a difference that was statistically significant, while the "as treated" analysis showed a significant difference. The study failed to adjust for lead-time bias. When adjusted for lead-time bias, the difference was no longer statistically significant. The failure to adjust for lead-time bias should lower the study's rating from "good" to "fair" or "poor." The lack of a wash-out period and the failure to adjust for lead-time bias is an indication that these researchers were not properly educated in the elements of proper study design, or they purposely ignored these principles in order to obtain the desired outcomes.

Statement 123: "In the Uganda study, the risk of HSV-2 infection (adjusted for other factors) was 28% lower in circumcised men.[71]"

Comment: **Misleading, incomplete**. While the authors reported a significant reduction in HSV infection in men who were circumcised, when adjusted for lead-time bias, their results were no longer statistically significant.[Storms 2009]

Statement 124: "There is fair evidence from 1 study that male circumcision protects female partners against HSV-2 infection.[33]"

Comment: Accurate. For this study only.

Statement 125: "Two studies with fair evidence found that there is no effect of circumcision on the risk of HSV-2 acquisition.[6,74]"

Comment: **Misleading**. Reference 6 should be labeled as "good" while Reference 74 should be labeled as "excellent".

Statement 126: "Chancroid is a bacterial disease spread through sexual contact. It is rare in the United States, with a total of 24 cases reported in 2010 (a rate of 0.08 case per 100 000 individuals).[75]"

Comment: Accurate, but irrelevant. If this is so rare in the United States, why is it even being discussed?

Statement 127: "The literature search produced no individual studies since 1995 exploring the relationship between male circumcision and chancroid."

Comment: Accurate, but irrelevant.

Statement 128: "One meta-analysis with good evidence found that 6 of 7 older studies (85%) described circumcision as having a protective effect against chancroid. This meta-analysis did not provide a summary value for the relationship due to differences in the definition and ascertainment of outcomes and variability among the comparison groups.[68]"

Comment: **Misleading, inconsistent with the medical evidence**. This published meta-analysis of chancroid included studies that did not meet basic inclusion criteria. In two African trials, men with GUD were presumed to have chancroid,[Cameron et al 1989, Nasio et al 1996] while in another study only 22.9% of men with GUD cultured *H. ducreyi*, while 31.4% yielded herpes, yet all of the men with GUD in this study were considered to have chancroid for the purposes of the meta-analysis.[Barile et al 1962] How can this be considered "good evidence" when three of the studies believed to have documented cases of chancroid did not accurately document chancroid?

Statement 129: "One methodologically poor meta-analysis found no effect of male circumcision on chancroid.[76]"

Comment: **Wrong citation provided, biased evaluation**. It is likely they were referring to Reference 78. The Task Force characterized this meta-analysis, which did not include the three studies erroneously included in Reference 68 because they did not meet basic inclusion criteria, [Cameron et al 1989, Nasio et al 1996, Barile et al 1962] as "poor" not because of the methodology used, which was the same as the meta-analysis that was characterized as "good" above, but likely because the results did not agree with their agenda. This reflects poorly on the integrity and professionalism of the Task Force and the epidemiologist involved.

Statement 130: "The CDC reports that the frequency of lymphogranuloma venereum infection is thought to be rare in industrialized countries, although its identification is not always obvious; the number of cases of this infection in the United States is unknown.[77]"

Comment: **Irrelevant**. If this is so rare in the United States, why take up space with this when the basic anatomy and physiology of the foreskin are not even discussed?

Statement 131: "Granuloma inguinale is a genital ulcerative disease that is rare in the United States but endemic in some tropical and developing areas. The lesions might develop secondary bacterial infection or can coexist with other sexually transmitted pathogens."

Comment: Irrelevant. See Statement 130.

Statement 132: "The literature search produced no studies since 1995 exploring the relationship between male circumcision and lymphogranuloma venereum or granuloma inguinale."

Comment: **Irrelevant**. If there are no new studies and these diseases are rare, why did the AAP waste space on this? Is there any old evidence that might be worth discussing? This space could have been used to address the anatomy and physiology of the foreskin or non-specific urethritis.

Statement 133: "One meta-analysis provided fair evidence that genital ulcerative disease was more common in uncircumcised men but not to a statistically significant degree.[78]"

Comment: **Inaccurate, internally inconsistent, schizophrenic**. Reference 78 found that men with an intact penis were at greater risk for GUD and the difference was statistically significant (intact versus circumcised: OR=1.34, 95%CI=0.98-1.82). It is interesting that the paper that presented a meta-analysis that found no difference in chancroid infections was characterized by the Task Force as "methodologically poor", yet the *same* paper that presented a meta-analysis that found circumcised men at lower risk for GUD is characterized as "fair evidence." It seems that the "quality" of the evidence depends on whether the evidence supports circumcision or not.

Still, there is no reason why the evidence in this publication should not be considered "good" instead of "fair" or "poor."

Statement 134: "One cross-sectional study with fair evidence found that male circumcision was protective against genital ulcers, but the findings were based on respondents self-reporting a history of genital ulcerative disease and may not be accurate.[79]"

Comment: **Misleading**. This study relied on patient report for both circumcision status and whether the subject had a genital discharge or genital ulcer in the previous 12 months. Because of the inaccuracy of patient reports for both of these entities, which is weakly defensible in its class, this study is of "poor" quality, not "fair" quality. It is confusing why this study should be singled out when there are many studies of GUD and GDS that are of much better quality.[ref 36, ref 37, ref 47, ref 49, ref 53, ref 71, ref 86, Agot et al 2004, Bailey et al 1999, Barile et al 1962, Institut du Statistiques (Burundi) 2012, Bwayo et al 1994, Cameron et al 1989, Mehta et al 2012, Nasio et al 1996, Newell et al 1993, Simonsen et al 1988, Tyndall et al 1996]

Statement 135: "Nonulcerative STIs generally cause inflammation and scarring along the reproductive tract. Untreated infection can cause cancer, can interfere with reproduction, and can negatively impact newborn health. Additionally, these infections can facilitate the transmission of HIV."

Comment: **Hyperbole**. Without stating the actual risks of cancer, interference with reproduction, impact on newborn health, and impact on HIV transmission this can be seen as a scare tactic. Newborns aren't at risk for STIs except through vertical transmission.

Statement 136: "BV is a condition "in women where the normal balance of bacteria in the vagina is disrupted and replaced by an overgrowth of certain bacteria."[80] BV is common among pregnant women; an estimated 1 080 000 pregnant women have BV annually."

Comment: Accurate.

Statement 137: "There is good evidence from 1 large randomized controlled trial that male circumcision is protective against BV in female partners.[81]"

Comment: **Misleading, inaccurate**: Considering that the BV diagnosis is based on a 10 point scale and the intervention group had significantly more BV at the beginning of the trial (38.6% versus 30.6%), this study is "fair" evidence, not "good" evidence. BV is common in females with circumcised partners. It is one of the most common cause of vaginitis and of female complaints bringing women to see their physicians in the US. There are other factors that contribute to BV such as hormonal changes, antibiotic use, frequency of sexual activity, number of sexual partners, etc., so it is difficult to identify the male foreskin as a risk factor. Obviously more study is needed. If circumcision is protective, then why do women present with this complaint so frequently when most adult males in this country are circumcised?

Statement 138: "A small prospective cohort study with good evidence also found that male circumcision, among other factors, was protective against BV in female partners.[82]"

Comment: **Misleading, inaccurate**. This study reported a hazard ratio of 1.9 (95%CI= 1.0-3.5, p=.04) for both univariate and multivariate analysis. Given how the data was collected and reported (as number of events per time of exposure), Poisson regression, instead of Cox proportional hazards (which are used primarily to measure time to event), should have been the statistical method used. If Poisson regression is used, as it should have been, the relative risk is 1.70 (95%CI=0.87-3.31, p=.1187). There were only 15 women-years with a partner with an intact penis and 9 infections. These small numbers make this "fair" evidence rather than "good" evidence. Again, BV is seen commonly in the US despite high rates of male circumcision, and there are many other factors at play with BV.

Statement 139: "A cross-sectional study with fair evidence found no effect but may have lacked the power to detect an effect.[83]"

Comment: **Misleading, incomplete, cherry picking**. One is never allowed to state "but may have lacked the power to detect an effect" because one does not have a crystal ball to know what further data collection will bring. This is like saying that Ted Williams would have surpassed Babe Ruth in the number of career home runs if he had not joined the armed forces in World War II and the Korean War. There is no way of predicting what didn't happen. Instead, the recommended practice is to report the odds ratio and the 95% confidence interval. In this study, the odds ratio was 1.198 (95%CI=0.678-2.118). The Task Force failed to identify a study of "fair to good" quality that did not find an association between sex with a circumcised partner and BV infection (OR=1.07, 95%CI=0.95-1.21).[Schwebke & Desmond 2005] This is an obvious example of cherry-picking.

Statement 140: "Chlamydia is the most commonly reported notifiable disease in the United States and the most common STI reported to the CDC, with 1 307 893 chlamydial infections (426.0 cases per 100 000 individuals) reported to the CDC in 2010.[84]"

Comment: Accurate.

Statement 141: "The balance of evidence does not reveal any relationship between circumcision and chlamydia infection.[85–87]"

Comment: **Incomplete, misrepresents the literature, major topics not addressed**. This has also been addressed in a meta-analysis, which did not find a statistically significant association. [ref 78] The meta-analysis was able to identify more than three studies.[ref 47, ref 49, ref 135, Auvert et al 2001, Aynaud et al 1999, Cook et al 1994, Dave et al 2003, Hart 1993, Parker et al 1983] Since publication of the meta-analysis, five studies have likewise found no statistically

significant association.[ref 73, 134, Mehta et al 2009, Ferris et al 2010, Rodriguez-Diaz et al 2012]

<u>Update</u>: This is consistent with the most recent meta-analysis published (intact versus *circumcised: prevalence OR=0.91, 95%CI=0.72-1.15, incidence RR=1.20, 95%CI=0.96-1.49).* [Van Howe (STI) 2013] The Task Force misrepresented the medical literature in citing Reference 85 to support their statement. This study did not present data on the relationship between circumcision and genital chlamydial infection, but rather the risk of any STI based on circumcision status. The studies that assessed the risk of any STI (as opposed to being STI-free) by circumcision status are otherwise ignored by the Task Force. [ref 51, ref 87, ref 88, ref 92, ref 134, ref 135, Auvert et al 2001, Aynaud et al 1999, Institut du Statistique (Burundi) 2012, Cook et al 1994, Dave et al 2003, Ferris et al 2010, Gebremedhin et al 2010, Harberson et al 2013, Klavs & Hamers 2008, Langeni 2005, Parker et al 1983, Rodriguez-Diaz et al 2012, Schrek & Lenowitz 1947, See et al 1995, Taylor & Rodin 1975] The reason for these being ignored may be that intact men are at significantly lower risk of any STI (summary OR=0.82, 95%CI=0.74-0.92). [Van Howe (STI) 2013] Similarly, The Task Force does not include a discussion of non-specific urethritis, which is a common STI. The relationship between circumcision and non-specific urethritis has been addressed in a number of studies[ref 49, ref 134, ref 135, Aynaud et al 1999, Cook 1994, Dave et al 2003, Donovan et al 1994, Ferris et al 2010, Parker et al 1983, Smith et al 1987, Taylor & Rodin 1975, Wilson 1947] and two metaanalyses. [ref 78, Van Howe (STI) 2013] It should come as no surprise that intact men are at significantly lower risk of non-specific urethritis (summary OR=0.76, 95%0.63-0.92).[Van Howe (STI) 2013] Many of the studies listed as references in the Task Force report addressed these two issues, so the Task Force can reasonably have been expected to address them. The question is why they chose to ignore two issues for which the medical literature is not favorable to circumcision.

Statement 142: "The 1 prospective cohort study with fair evidence showed a protective effect, but the study had a composite end point with several STIs combined and used self-report of STI as the outcome (increasing the possibility of misclassification).[88]"

Comment: **Misleading, incomplete**. This study showed no significant difference. The number of men reporting infection was small (22), thus the confidence interval was broad (OR=2.50, 0.73-8.53). Because of the small number of infected men this study should have been labeled "poor" quality. Other prospective studies have been published and ignored by the Task Force.[ref 73, ref 87, Mehta et al 2009] When the results are combined in a meta-analysis, no significant association is present (intact versus circumcised: RR=1.20, 95%CI=0.96-1.49). Not sure why the Task Force ignored studies in their reference list.

Statement 143: "Two studies with fair evidence explored the effect of male circumcision on chlamydia infection in female partners. The first, a prospective cohort study, found a nonsignificant increased risk in the female partners of circumcised men.[89]"

Comment: Accurate. Adjusted hazard ratio (circumcised partner versus intact partner) was 1.25, 95%CI=0.96-1.63.

Statement 144: "The second, a cross-sectional study, found a significantly decreased risk of chlamydia infection among women with circumcised male sexual partners, but a possible selection bias may have affected results because only 51.8% of subjects had specimens for analysis.[90]"

Comment: **Incomplete**: This study had more problems than selection bias. The study was from five countries, so in the raw analysis there would be five 2X2 tables and a total of 20 cells. Of these 20 cells, ten cells had fewer than 10 events and eight cells had five or fewer events. The statistical methods used in the analysis could not generate meaningful or reliable results. The question is why the Task Force mentioned this methodologically crippled study of obviously "unsatisfactory" quality yet fails to include a discussion of non-specific urethritis.

Statement 145: "Gonorrhea is the second most commonly reported STI in the United States, with 309 341 cases reported to the CDC (a rate of 100.8 cases per 100000 individuals) in 2010.[91]"

Comment: Accurate.

The evidence does not demonstrate any relationship between circumcision and gonorrheal infection.[85,86,92–94]"

Comment: **Incomplete/Inaccurate, misrepresents the literature**. The Task Force only looked at a select portion of the medical literature missing several studies[ref 47, ref 49, ref 87, ref 94, ref 135, Aynaud et al 1999, Bailey et al 1999, Cook et al 1994, Dave et al 2003, Donovan et al 1994, Hand 1949, Hart 1993, Lloyd & Lloyd 1934, Parker et al 1983, Schrek & Lenowitz 1947, Smith et al 1987, Taylor & Rodin 1975, Wilson 1947] that had also been addressed in a meta-analysis, which did not find a statistically significant association.[ref 78] Since publication of the meta-analysis other studies have likewise found no statistically significant association.[ref 73, ref 102, ref 134, Mehta et al 2009, Ferris et al 2010, Rodriguez-Diaz et al 2012] Neither Reference 85 nor Reference 92 evaluated the relationship between circumcision and gonorrheal infection. With eight additional studies in their reference list that could have been cited, it is unclear why the Task Force cited two studies that did not address the topic. The Task Force did correctly conclude that there is no relationship between circumcision and gonorrheal infection.

<u>Update</u>: This is consistent with the most recent meta-analysis published which showed no difference in incidence or prevalence (intact versus circumcised: prevalence OR=1.03, 95%CI=0.86-1.23, incidence RR=1.04, 0.86-1.27).[Van Howe (STI) 2013]

Statement 146: [Under the heading of Gonorrhea] "The studies that show a protective effect are either barely significant or have poorly defined or self-reported outcomes, thus offering only a fair level of evidence.[79,88]"

Comment: **Misrepresentation, inappropriate citation**. Reference 79 did not test for or inquire specifically about gonorrhea. Reference 88 had only two reported cases of gonorrhea and did not perform an analysis of these two cases.

Statement 147: "HPV is among the most commonly occurring STIs in the United States and can lead to the development of cancers, including cervical cancer. The population-based data from NHANES 2003–2006 indicate that the overall prevalence of high- and low-oncogenic risk HPV types was 42.5% among US women aged 14 to 59 years. The prevalence of infection was lower for the 2 viral types with the highest risk of causing cancer, however, at 4.7% for HPV type 16 and 1.9% for HPV type 18.[95]"

Comment: Accurate. It should be noted that there are currently vaccines effective in reducing the carriage of oncogenic strains of HPV for both males and females. Also, most HPV infections are transient.

Statement 148: "There is good evidence that male circumcision is protective against all types of HPV infection (nononcogenic and oncogenic)."

Comment: **Unsubstantiated, misleading, incomplete, false**. A meta-analysis of HPV infection in men failed to find a difference in infection rates based on circumcision status. Most of the studies suffered from sampling bias and misclassification bias. There was a statistically significant difference in the odds ratios reported in studies that did not completely sample the penis for HPV and that relied on patient report for circumcision status. When adjusted for the impact of these forms of bias, there was no difference in risk.[Van Howe (HPV) 2007, Van Howe & Storms 2009] Other meta-analyses have been published, but none of them adjusted for significant confounding factors in the study designs. There are only a few studies that have performed adequate sampling of the penis for HPV and determined circumcision status by physical examination. These studies have consistently failed to find an association between circumcision status and HPV, so overall there is limited "good evidence" and the "good evidence" fails to shown an association. For example, no association was found in men attending the University of Washington between HPV infection and circumcision status.[Weaver et al 2004, VanBuskirk et al 2011] Given the sampling bias and misclassification bias in most of the studies, this is not "good" evidence.

<u>Update</u>: The HIM study failed to find an association between HPV infection and the presence of a foreskin. In fact, intact men were at slightly lower risk of infection with HPV, and intact men shed the virus significantly more quickly.[Albero et al 2014] When the HIM study is combined in a meta-analysis with other prospective studies of incidence and circumcision status, the fixed-effect relative risk (intact versus circumcised) is 1.05 (95%CI=0.88-1.25), indicating no statistically significant difference.

Statement 149: "Two prevalence studies with good evidence found a 30% to 40% reduction in risk of infection among circumcised men.[96,97] These studies fail to provide information on the risk of acquiring HPV and may reflect persistence of HPV rather than acquisition of infection."

Comment: **Misleading, incomplete**. Reference 96 drew approximately one-third each of its participants from Brazil, Mexico, and the United States. The participants from Brazil had high HPV rates and low circumcision rates. The US participants had high circumcision rates. The way the study is designed, and because of colinearity issues, it is impossible to tell if the lower rates of HPV in circumcised men is because of circumcision itself or because the men did not live in Brazil where there is likely higher rates of HPV exposure. Because of these problems, this is not "good" evidence, but "fair" or "poor" evidence. Reference 97 failed to find a significant association between either oncogenic or nononcogenic HPV detected at any genital site and circumcision status.

<u>Update</u>: The study of Brazil, Mexico and United States was the HIM study, that stratified by country when it published its incidence results, which showed no association with circumcision status.[Albero et al 2014]

Statement 150: "Four studies provide fair evidence that male circumcision protects against HPV. [98–101]"

Comment: Unsubstantiated, misleading, incomplete, cherry picking. Reference 98 reports a difference in the rate of recovery of HPV from the glans and corona in the abstract, but there was no difference in overall HPV recovery by circumcision status. Reference 99 failed to adjust for ethnicity, so it is not clear if the difference was because of difference in exposure from within an ethnic community or from circumcision. They also did not obtain adequate samples. Sampling bias will underestimate the prevalence of HPV in circumcised men by about 30%. See Statement 151. Because of this sampling bias, this study is "poor" evidence. Reference 100 involved data taken from 5 countries. In two of the countries circumcision status was based on patient report. This study also failed to obtain adequate samples. Of the 20 cells, seven had populations of 5 or less, making the statistical methods they used unstable. Because of the sampling bias, relying on patient report for circumcision status, and limitations of the data (small cell sizes) this is also "poor" evidence. Reference 101 findings were not statistically significant (adjusted OR=2.5, 95%CI=0.6-12.5). There were only 24 circumcised males, in whom only 2 were found to have an oncogenic HPV infection. This study had adequate sampling. There are number of studies the Task Force failed to consider. [Aynaud et al 1994, Aynaud et al 1999, Bleekeret al 2005, Lajous et al 2005, Mandal et al 1991, Müller et al 2010, O Ng'ao et al (HPV) 2008, Ogilvie et al 2009, Oriel 1971, Shin et al 2004, Vaccarella et al 2006, Vardas et al 2011, Weaver et al 2004] The Task Force also failed to evaluate the relationship between circumcision and genital warts. The topic has been well studied and addressed in several of the references in the Task Force report.[ref 49, ref 120, ref 134, Cook et al 1994, Dave et al 2003, Dinh et al 2008, Donovan et al 1994, Ferris et al 2010, Mallon et al 2000, Parker et al 1983, Rodriguez-Diaz et al 2012, Van Den Eeden et al

1998, Wilson 1947] There is a trend that intact men are less likely to have genital warts (intact versus circumcised: OR=0.82, 95%CI=0.65-1.04). [Van Howe (STI) 2013]

Statement 151: "The selection of anatomic sites sampled may influence the results.[98]"

Comment: **Accurate, incomplete**. There are several other studies that have also documented this.[ref 98, Weaver et al 2004, VanBuskirk et al 2011, Aynaud et al 1994, Aynaud et al 1999, Oriel 1971] In one study of men with HPV found anywhere in the genital region, the glans of 65% of intact men will have HPV, but only 48% of HPV-infected circumcised men will have HPV detected on the glans.[Weaver et al 2004] Similar findings were also noted by Van Buskirk et al. in which only 45% of HPV-infected circumcised men will have HPV detected on the glans versus 66% of HPV-infected intact men.[VanBuskirk et al 2011] If one were to take a group of circumcised and intact men who had an equal prevalence of HPV infection and sample only the glans, this would detect HPV 30% more often in the intact men, even though the two groups had the same incidence. Thus, a 30% difference can be explained by improper sampling. HPV-infected circumcised men are more likely to have lesions found only on the penile shaft. HPV lesions on the shaft of the penis carry higher viral loads and is the preferred location for HPV 16, the most oncogenic HPV type.[Flores et al 2008] This would suggest that circumcised men would be even more likely to pass on HPV 16 to their partners, which increases the risk of cervical and other cancers.

Statement 152: "Good evidence of the protective effect of male circumcision against HPV is available from two of the large randomized controlled trials in Africa."

Comment: **Misleading, biased, incomplete**. See discussion below. The HPV study from the Kenyan randomized trial has been released, but the direct comparison data of HPV infections by circumcision status was not reported. From looking at the data reported, it appears as though this study found no difference in HPV infections by circumcision status.[Backes et al 2012] The Task Force also failed to include other prospective studies. [Dickson et al 2009, Lajous et al 2009, Lu et al 2009, Partridge et al 2007, VanBuskirk 2011] When all of the prospective studies are put in a meta-analysis and adjusted for sampling bias and lead-time bias there is no relationship between circumcision and the incidence of oncogenic HPV.[Van Howe (STI) 2013]

<u>Update</u>: When the results of the HIM study[Albero et al 2014] are added there is no association (RR=1.05, 0.88-1.25).

Statement 153: "In the South African study, the prevalence of high-risk HPV was 32% lower in circumcised men.[102]"

Comment: **Misleading, biased**. Reference 102 did not assess *prevalence*, but attempted to assess *incidence*. This is another example of the lack of attention paid to this report by the Task Force. This study failed to adequately sample the entire penis. Consequently, the rate of HPV infections in circumcised men would be underestimated by about 30%. When adjusted for this sampling

bias, their intention-to-treat odds ratio (circumcised versus intact) is 0.87 (95%CI=0.66-1.14) and the result is no longer statistically significant.[Van Howe 2009] Consequently, sampling bias can explain their positive findings. Because of the sampling bias, this not "good" evidence but "poor" evidence. The study also failed to adjust for lead-time bias.

Statement 154: "In the Uganda study, the risk of oncogenic HPV infection (adjusted for other factors) was 35% lower in circumcised men.[71]"

Comment: **Misleading, biased**. This study failed to adequately sample the entire penis. Consequently, the rate of HPV infections in circumcised men would be underestimated. When adjusted for this sampling bias, the odds ratio (circumcised versus intact) is 0.83 (95%CI=0.56-1.24) and the result is no longer statistically significant.[Storms 2009] Consequently, sampling bias can explain their positive findings. Because of the sampling bias, this is not "good" evidence but "poor" evidence. The study also failed to adjust for lead-time bias.

Statement 155: "There is also good evidence that male circumcision reduces the risk of male-tofemale transmission of high-risk HPV from HIV-uninfected men. In the Uganda randomized controlled trial, the prevalence of high-risk HPV infection was 28% lower in female partners of circumcised HIV-uninfected men, while the incidence was 23% lower.[32]"

Comment: Misleading, incomplete. Reference 32 has several problems. First, there was no effort to determine the source of infections and no evidence that these women became infected from their husbands. Second, the test used to determine HPV infection has a sensitivity of only 74% and a positive likelihood ratio of 6 (not good). Third, condom use was associated with higher infection rates, which makes no sense. Fourth, when the trial started, women reporting only one sexual partner in the past year had an HPV prevalence of 55% using a test that would miss 26% of the infections. Fifth, 99% of the women reported no extra-marital partners during the two-year trial, which sounds too good to be true. Sixth, HPV 16 and 18 account for 70% of cervical cancers, yet this study found no difference in the incidence of these strains between women with circumcised and intact husbands. The study focuses on relatively inconsequential HPV strains that are less likely to cause cancer. Seventh, 17% of the women were lost to followup, yet there was no mention of their baseline HPV prevalence. Based on these, it is not "good" evidence but, at the very best, "fair" evidence. In a study of women attending the University of Washington, no difference was found in HPV rates based on the circumcision status of the male sexual partner.[Winer et al 2003] The report and, surprisingly, Reference 32 make no mention of this study, which would be of "fair to good" quality. Did the authors of Reference 32 forget to review the medical literature before submitting their manuscript, or did they decide to exclude mention of the only other study that had been published on the subject of their study? In either case, the investigators from Johns Hopkins need to explain this academic deficiency.

Statement 156: "Good evidence from another Uganda randomized controlled trial of male circumcision in HIV-infected men indicates that circumcision did not reduce the risk of male-to-female transmission of high-risk HPV from HIV-infected men.[103]"

Comment: **Misleading**. Reference 103 shares the same methodological flaws as Reference 32. See Statement 155.

Statement 157: "According to the CDC, "A urinary tract infection (UTI) is an infection involving any part of the urinary system, including urethra, bladder, ureters, and kidney."[104] UTIs are the most common type of health care–associated infection reported to the National Healthcare Safety Network among US individuals. The majority of UTIs in males occur during the first year of life."

Comment: Accurate, incomplete. With the other CDC reports on STIs, the incidence of these infections is given. Why is the incidence of UTIs in children not given?

Statement 158: "In children, UTIs usually necessitate a physician visit and may involve the possibility of an invasive procedure and hospitalization."

Comment: **Unclear, incomplete, hyperbole**. By an "invasive procedure" does the Task Force mean catheterization or suprapubic aspiration to obtain a specimen, or some other procedure? (Is this language intended as a scare tactic in order to justify promoting circumcision?) Also, UTIs may not be as serious as previously believed. For example, it has been shown that oral antibiotics are as effective as intravenous antibiotics in treating infants with UTIs.[Hoberman et al 1999] It has also been shown that UTIs occurring in the first twelve months of life are less likely to result in renal parenchymal involvement.[Pecile et al 2009] The scare tactics of UTIs leading to long-term, and end-stage, renal damage have been shown to be unfounded. UTIs rarely if ever lead to hypertension or persistent renal dysfunction.[Sreenarasimhaiah & Hellerstein 1998, Helin & Winberg 1980, Esbjörner, Berg, & Hansson 1997, Esbjörner et al 1990, Wennerström et al 2000a, Wolfish et al 1993, Wennerström et al 2000b] The Task Force neglects to mention that males are more likely to have vesicoureteral reflux noted on prenatal ultrasound and, fortunately, most cases resolve spontaneously. This reflux temporarily predisposes males to UTIs.[Herndon et al 1999, Yeung et al 1997] In their 2011 statement on UTIs, the AAP recommends evaluations of children with UTIs be less invasive.[Subcommittee on UTI 2011]

<u>Update</u>: A 2011 systematic literature review found that a child with normal kidneys is not at risk for developing chronic kidney disease as an aftermath of UTIs.[Salo et al 2011]

Statement 159: "Most available data were published before 1995 and consistently show an association between the lack of circumcision and increased risk of UTI. Studies published since 1995 have similar findings."

Comment: **Inaccurate, incomplete** . Several studies from Israel have found a higher risk of UTIs in circumcised boys, compared to girls, in the first several months of life.[Amir et al 1986, Amir et al 1984, Goldman et al 1996, Cohen et al 1992, Prais et al 2009, Toker et al 2010] Typically girls have higher UTI rates at this age. This difference may be from the tight bandages wrapped around the circumcision wound in traditional circumcision, which may impede urine flow. There are also suggestions that meddling with the foreskin in the first months of life may increase UTIs similar to what is seen with "honeymoon cystitis." Also, the urinary tract infection rates in European countries where circumcision rates are low has not prompted them to adopt circumcision as a health measure. Instead, several countries in Europe have denounced the practice. The emphasis on circumcision also draws attention away from the actual anatomic defects that may be associated with UTIs.

Statement 160: "There is good evidence from 2 well-conducted meta-analyses[105,106] and a cohort study[107] that UTI incidence among boys under age 2 years is reduced in those who were circumcised compared with uncircumcised boys."

Comment: **Incomplete/False**. The Task Force fails to mention that only *observation* studies have been published. These studies have a variety of confounding factors that may bias the results. A model was published that took these confounding factors into account. It found that, if it is assumed that UTIs occur in the first year of life equally in those who are circumcised and in those with an intact penis, the diagnosis of UTI would be made in intact males 4.27 times more frequently than in circumcised males. This would make it look like they were 4.27 times more likely to have a UTI, when in reality they were at the same risk. Consequently, reported differences in the rate of UTI by circumcision status may be entirely attributed to sampling and selection bias.[Van Howe 2005]

Statement 161: "The data from randomized controlled trials are limited. However, there are large cohort and case-controlled studies with similar findings. Given that the risk of UTI among this population is approximately 1%, the number needed to circumcise to prevent UTI is approximately 100."

Comment: **Misleading, inaccurate**. There have been no randomized controlled trials in regards to circumcision and UTI, so how can the data be limited? By making this statement the Task Force is implying that randomized controlled trial data exists when it does not. This calculation assumes, that if the UTI rate is 1%, circumcision would eliminate all UTIs, which it does not. One meta-analysis puts the number needed to treat at 111.[ref 106] Others have estimated the number needed to treat to be 195.[ref 107] If the cost of infant circumcision is \$285[Hart-Cooper et al 2014], the cost to prevent one UTI would be between \$31,635 and \$55,575. This is a large expenditure for an infection that can be treated with an \$18 oral antibiotic.

Statement 162: "The benefits of male circumcision are, therefore, likely to be greater in boys at higher risk of UTI, such as male infants with underlying anatomic defects such as reflux or recurrent UTIs."

Comment: **Speculation**. While this "expert" opinion has been circulated for more than a decade, the evidence to support it is lacking.

<u>Update</u>: Following this "expert" advice a study in Scotland found that only 3% of boys diagnosed with UTI met the criteria for which circumcision might be recommended.[Broadis et al 2015] Given that only 1% of boys will have a UTI, this means that a circumcision would be indicated, related to UTI, in 1 in 3333 boys.

Statement 163: "There is fair evidence from 5 observational studies that UTI incidence among boys under age 2 years is reduced in circumcised infant boys, compared with uncircumcised boys under the age of 2.[108–112] The degree of reduction is between threefold and 10-fold in all studies."

Comment: **Misleading, incomplete**. Reference 110 only performed a chart review on a third of the patients identified as having a UTI. Also, the study did not exclude boys with urinary tract anomalies. For such an analysis, the failure to adequately collect information puts this in either the "poor" or "unsatisfactory" category. The report fails to mention seven studies from Israel that found a spike in UTIs in the weeks following ritual circumcision. The rate of UTIs was much higher than in girls.[Amir et al 1984, Amir et al 1986, Goldman et al 1996, Cohen et al 1992, Harel et al 2002, Prias 2009, Tokar et al 2010]

Statement 164: "There is fair evidence from a prospective study that there is a decreased prevalence of uropathogens in the periurethral area 3 weeks after circumcision, compared with similar cultures taken at the time of circumcision.[113]"

Comment: **Misleading, redundant**. With circumcision, the gram-negative bacteria are replaced with gram-positive bacteria. Pathogenicity is in the eyes of the beholder. This explains why MRSA infections in the newborn period affect circumcised males 12 times more frequently than those left intact.[ref 210] Other staphylococcal infections are more likely in circumcised newborns as well.[Thompson et al 1966, Enzenauer et al 1985, Rush et al 1990]

Statement 165: "By using these rates and the increased risks suggested from the literature, it is estimated that 7 to 14 of 1000 uncircumcised male infants will develop a UTI during the first year of life, compared with 1 to 2 infants among 1000 circumcised male infants."

Comment: Unsubstantiated. No citation given.

Statement 166: "There is a biologically plausible explanation for the relationship between an intact foreskin and an increased association of UTI during infancy. Increased periurethral bacterial colonization may be a risk factor for UTI.[114] During the first 6 months of life, there are more uropathogenic organisms around the urethral meatus of uncircumcised male infants

than around those of circumcised male infants (this colonization decreases in both groups after the first 6 months).[115]"

Comment: **Misleading, redundant**. See Statement 164. The surfaces of our skin and mucosal membranes (such as our upper respiratory tract, mouth, colon, and genitals) are covered with bacteria and other micro-organisms. This is considered *normal* flora. Bacteria that are part of our normal flora can cause disease if they overpopulate (such as yeast in a diaper rash or thrush) or if they colonize in inappropriate places (such as bacteria in the lungs). The fact that we have bacteria in our mouths that would result in pneumonia if these bacteria were in our lungs does not mean that the presence of the bacteria in our mouths is abnormal or that the mouth should be sterilized. The same principle applies to the normal periurethral flora. In addition, the tip of the foreskin acts as a one-way valve to keep contaminants out. It is when the opening of the urethra is manipulated, as is seen when parents are given the inappropriate advice to retract the foreskin, that the likelihood of the flora becoming displaced occurs. The urethra is flushed with sterile urine several times a day to minimize its bacterial colonization.

Statement 167: "In addition, an experimental preparation found that uropathogenic bacteria adhered to, and readily colonized, the mucosal surface of the foreskin but did not adhere to the keratinized skin surface of the foreskin.[116]"

Comment: **Misleading**. Since Reference 116 was published in 1988 (before the time period they supposedly were looking at), it has been found that uropathogenic bacteria adhering to mucosal surfaces are less likely to cause kidney scarring and damage. While they are more likely to colonize, they are less likely to cause chronic damage or symptoms requiring treatment.

Statement 168: "Penile cancer is rare, and rates seem to be declining. In the United States, Surveillance, Epidemiology, and End Results data indicate that the incidence of primary, malignant penile cancer was 0.58 case per 100 000 individuals for 1993 to 2002, a decline from 0.84 case per 100 000 individuals from 1973 to 1982.[117] An analysis of the Danish Cancer Registry found that the incidence of epidermoid cancer of the penis (excluding scrotal, epididymal, and nonepidermoid) declined from a rate of 1.15 cases per 100 000 individuals from 1943 to 1947 to 0.82 case per 100 000 individuals in 1988 to 1990.[118] Thus, declines have been noted in nations with both low and high circumcision rates (Denmark and the United States, respectively). Declines are not explained by changing patterns in circumcision utilization; it is thought that socioeconomic and economic development factors (including effects on hygiene habits) may have an important role."

Comment: **Incomplete**. The penile cancer rates are higher in the Unites States than in Norway and Finland, among other countries. [Iversen et al 1997, Maiche 1992] Changes in penile cancer rates could be secondary to declining smoking rates. One would expect a decrease in cancer rates with circumcision proportional to the amount of tissue amputated that cannot now become cancerous. For example, if the left testicle were removed from all boys, testicular cancer would be decreased by more than half because more testicular cancers are in the left testicle.

Statement 169: "The literature review yielded 2 case-control studies; although the studies were well designed, the evidence level for case-control studies is only deemed to be fair.[119,120] These studies show an association between circumcision and a decreased likelihood of invasive penile cancer. For all men with penile cancer (carcinoma in situ and squamous cell carcinoma), the absence of circumcision confers an increased risk with an odds ratio (OR) of 1.5, although this finding was not significant (P = .07), with a CI of 1.1-2.2.119 An OR indicates the odds of an event happening in 1 group divided by the odds of an event happening in another group. An OR of 1 thus means that there is an equal chance for the event to occur in each group. When separated into squamous cell carcinoma and carcinoma in situ, the absence of circumcision was a risk factor for invasive squamous cell carcinoma (OR: 2.3 [CI: 1.3-4.1]) but not for carcinoma in situ (OR: 1.1 [CI not provided])."

Comment: **Incomplete**. Since penile cancer is extremely rare, this would suggest that addressing the causes and treatment of pathologic phimosis would be more effective than circumcising thousands of boys to prevent one case of penile cancer. Before labeling all case-control studies as being of "fair" quality, the Task Force should acknowledge that for rare illnesses such as penile cancer it is practically impossible to perform a cohort study or a randomized clinical trial. To execute either of these study designs would require enrolling millions of men. Consequently, the best way to study an illness more rare than male breast cancer is to do a case-control study. The Task Force, by their wording, implies that better study methods are available. But, in fact, case-control studies are the best tool available for this rare cancer.

Statement 170: "Phimosis is a condition in which the foreskin cannot be fully retracted from the penis. A history of phimosis alone confers a significantly elevated risk of invasive cancer (OR: 11.4). In fact, in men with an intact prepuce and no phimosis, there is a decreased risk of invasive penile cancer (OR: 0.5). When excluding phimosis, the risk disappears, which suggests that the benefit of circumcision is conferred by reducing the risk of phimosis and that the phimosis is responsible for the increased risk. Other forms of penile injury or irritation likewise can pose a significant risk factor for cancer."

Comment: **Incomplete, misleading**. The most common cause of pathologic phimosis is balanitis xerotica obliterans, which has a cumulative risk of about 6 per thousand intact males by age 15 years.[Shankar & Rickwood 1999] Mild cases can be treated with topical steroids. Occasionally surgery is needed. There is growing evidence that BXO is a pre-malignant condition, which may explain why half of the penile cancer cases are not related to HPV infection.[Velazquez & Cubilla 2003, Powell et al 2000, Pietrzak et al 2006] Smoking is also a significant risk factor.[ref 119, 120] Smegma is not carcinogenic.[Van Howe & Hodges 2006] From this statement, it appears the goal should be an intact prepuce without phimosis, rather than a circumcised penis. Males should be monitored for the rare occurrence of BXO. Both studies note that when only men without phimosis were considered, circumcised men were not at different risk for invasive penile cancer (ref 119 OR=0.5, 95% 0.1-2.5; ref 120 OR=0.79, 95% CI=0.26-2.6). The number of

intact men without phimosis who developed invasive penile cancer was small in these studies. It should also be noted that the lead author in Reference 120 is Tseng not "Tsen."

Statement 171: "There is accumulating evidence that circumcised men have a lower prevalence of oncogenic (high-risk) and nononcogenic (low-risk) HPV when compared with uncircumcised men, and this may be another means by which circumcision has a protective effect against invasive penile cancer (as discussed in the earlier STI section)."

Comment: **Unsubstantiated, incomplete**. The "accumulating evidence," which is the result of cherry-picking the literature, is addressed in Statements 147 through 156. Only about half of penile cancers contain HPV DNA. As noted in Statement 170, BXO may be a precancerous condition.

Statement 172: "It is difficult to establish how many male circumcisions it would take to prevent a case of penile cancer, and at what cost economically and physically. One study with good evidence estimates that based on having to do 909 circumcisions to prevent 1 penile cancer event, 2 complications would be expected for every penile cancer event avoided.[121]"

Comment: **Misleading, inconsistent with medical evidence**. Reference 121 is a study based on information gathered from a database. Complication rates garnered from database studies consistently are 10 times lower than complication rates garnered from chart reviews. This study is "adequate" under the circumstances, but limited by using an incomplete database, thus providing only "fair" evidence. The estimate of doing 909 circumcisions to prevent one penile cancer was not measured in Reference 121, but came from the publication's discussion section that cites a 1980 opinion piece. This number was arrived at by using a number of baseless assumptions including that it was impossible for circumcised men to get penile cancer.[Kochen & McCurdy 1980]

Actually it's not difficult to estimate how many male circumcisions it would take to prevent one case of penile cancer. The Task Force had all the numbers at its disposal to make a rough estimate of the number needed to treat but failed to recognize this opportunity and act on it. The incidence of penile cancer according to the report is 0.58 per 100,000 person years. Because penile cancer is rare, the lifetime risk is the yearly incidence multiplied by 72 years, or 0.0004176 (see Statement 173). The Task Force report noted that the relative risk reduction for penile cancer by circumcision was between 1.5 and 2.3. If the lifetime risk of penile cancer is reduced by a factor of 2.3, 0.0001815 is obtained, which would be the expected lifetime risk for penile cancer in circumcised men. The absolute risk reduction would be the difference between the two rates: 0.0004176 minus 0.0001815 or 0.0002360. The number needed to treat is the inverse (1/x) of the absolute risk reduction or 4237. This means that 4237 infant males would need to be circumcised in order to prevent one case of penile cancer, which usually strikes on average at 80 years of age. If, however, the relative risk reduction is 1.5, the number needed to treat is 7184. These numbers are much higher than that speculated in Reference 121.

So, how much would it cost to prevent one case of penile cancer? If the cost of an infant circumcision is \$285[Hart-Cooper et al 2014], then 7184 circumcisions would cost \$2,047,440 up front. But this is only part of the cost. Because the money was spent at birth and penile cancer happens, on average, at 80 years of age, the opportunity costs of not having that money available for 80 years need to be considered. Discount rates of 3% and 5% are commonly used. With 3%, the cost to prevent one case of penile cancer is \$21.8 million, and with 5%, the cost is \$101.47 million. Not a wise use of resources. Even if the number needed to treat is 4237, the upfront cost is \$1,207,545 with the lost opportunity costs being \$12.8 million (3% discount rate) to \$56.8 million (5% discount rate). Again, not a wise use of resources. Not surprising that the Task Force did not include these estimates in their report.

Statement 173: "However, another study with fair evidence estimates that more than 322 000 newborn circumcisions are required to prevent 1 penile cancer event per year.[122]"

Comment: **Inaccurate**. It appears as though the author of Reference 122 failed to convert the rate per patient years to the rate per lifetime by dividing by 72, giving 4472.2, which is within the range discussed in Statement 172. (Dividing the yearly rate by average life expectancy gives a very close figure to that using the correct calculation formula (lifetime risk =1-(exp(-incidence X years), a result of 4472.7)

Statement 174: "This would translate into 644 complications per cancer event, by using the most favorable rate of complications, including rare but significant complications.[123]"

Comment: **Inaccurate, misleading**. Reference 123, like Reference 121, relies on information taken from databases, which will underestimate complication rates by a factor of 10 and miss 90% to 95% of the complications noted in the medical record. Therefore, in 322,000 circumcisions with an immediate complication rate of 2% (the most commonly accepted complication rate) there would be 6,440 complications. The 644 number would apply to serious/ life-threatening complications. For late complications, such as meatal stenosis for which approximately 5% (a conservative estimate given one study reported a rate of 20%,[Joudi et al 2011]) of circumcised males will require a meatotomy, for every 322,000 circumcisions you would expect 16,100 meatotomies. Of course, as discussed in Statement 173, the 322,000 is not accurate. This statement is misleading because the Task Force gives the impression that the complication rates derived from databases are accurate and valid, when they are not. Using complication rates derived from databases will portray circumcision in the most favorable fashion.

Statement 175: "The clinical value of the modest risk reduction from circumcision for a rare cancer is difficult to measure against the potential for complications from the procedure. In addition, these findings are likely to decrease with increasing rates of HPV vaccination in the United States."

Comment: **Incomplete**. Therefore, the promotion of circumcision by the AAP to supposedly prevent penile cancer, HPV, cervical cancer, etc. is misguided. Also, there is an effective vaccine for oncogenic strains of HPV currently available for males as well as for females.

Statement 176: "Up to 12000 new cases of cervical cancer are diagnosed in the United States annually. Cervical cancer is a leading cause of death for women in developing countries; more than 80% of all cervical cancer deaths occur in developing countries.[124] Persistent HPV infection with high-risk (ie, oncogenic) types (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82) is the main prerequisite to developing cervical squamous carcinoma."

Comment: Accurate.

Statement 177: "The association of cervical cancer, penile HPV infection, and circumcision was studied in an article of fair quality that found a protective effect of male circumcision against cervical cancer in the female partner(s) of men who have multiple female partners.100 There was a lower incidence of HPV detection in circumcised men compared with uncircumcised men (5.5% and 19.6%, respectively). The OR for men who self-reported having been circumcised and who had penile HPV was 0.37 (95% CI: 0.16–0.85). In women whose partner had more than 6 lifetime sexual partners, male circumcision lowered her odds of cervical cancer significantly (OR: 0.42). The overall rate of cervical cancer for women who currently had circumcised male partners was not significantly decreased. Thus, the contribution of male circumcision to prevention of cervical cancer is likely to be small."

Comment: Misleading, cherry picking, incomplete. Reference 100 failed to show a statistically significant difference overall. It is only by cherry picking a single stratum, out of many, that this finding was identified. When one goes stratum dredging, it is appropriate to apply a Bonferroni adjustment, which the authors failed to do. This result is also suspect because of the small number of circumcised men in four of the five countries taking part in the study and near universal circumcision in the fifth country. To split the data into several small strata and control for the country from which the data was generated in order to yield an accurate statistic would be impossible using the statistical methods they employed. These results would only apply to men who have multiple lifetime partners, not the general population, for whom this study found no difference. Therefore, if this study is valid, which it is not, and a male has multiple lifetime female partners, he may consider getting circumcised to protect his female partners, or he and his sexual partners can just get the HPV vaccine. As discussed above, the HPV results for the male participants were tainted by sampling bias and misclassification bias. Given that circumcision status was based on self-report, to be consistent, the Task Force should consider this study to be of "poor" quality. Including this study, there have been 16 studies that have attempted to find a significant association between cervical cancer and the circumcision status of male sexual partners, and all of them have failed. [Connon 1972, Aitken-Swan & Baird 1966, Abou-Daoud 1967, Wahi et al 1972, Zarkovic 1985, Boyd & Doll 1964, Jussawalla t al 1985, Kjaer et al 1991, Brinton et al 1989, Terris, Wilson, & Nelson 1973, Agarwal et al 1993, Rotkin 1973, Stern & Dixon 1961, Kmet et al 1963, Jones et al 1958] Following release of this report, one of the

talking points provided to AAP spokespeople was that circumcision prevented cervical cancer in female sexual partners. It is not clear why the AAP would willfully spread information that can easily be demonstrated not only to be inaccurate, but outright false. Did the AAP do this to promote genital surgery that makes a profit for physicians, or to protect physicians and hospitals from liability, or to protect certain religious rituals, or all of the above?

Penile Dermatoses and Phimosis

Statement 178: "Penile dermatoses encompass a wide range of genital skin diseases, some of which are rarer than others. These diseases can include psoriasis, inflammation (ie, balanitis, balanoposthitis), infections (ie, superficial skin and soft tissue infections such as cellulitis), lichen sclerosis, lichen planus, lichen simplex, seborrheic dermatitis, atopic eczema, and irritant dermatitis, among others."

Comment: Accurate.

Statement 179: "From 1995 to 2011, all publications addressing this concern were case series and were therefore excluded from the literature forming the current analysis."

Comment: **Inaccurate, incompetence**. Reference 76, a cross-sectional study of patients from a pediatric practice published in 1997 addressed these issues. How was this missed? Also missed was Mallon et al. (2000). As discussed elsewhere, the dismissal of all case series is a clear source of bias. While a single case series may not be definitive, a number of case series with similar findings does provide useful information that should be considered and weighted appropriately.

Statement 180: "Before 1995, a New Zealand prospective cohort study with good evidence explored rates of penile problems for 635 boys from birth to 8 years of age.[125] Four types of penile problems were defined: first was the number of episodes of inflammation of the penis experienced by the child. Penile inflammation included balanitis, meatitis, inflammation of the prepuce, and conditions in which the penis was described as sore or inflamed without any further diagnostic elaboration. The second type was the number of episodes of phimosis experienced by the child. These episodes included every time medical attention was sought for phimosis and associated symptoms. Episodes in which the child was brought to medical attention for "tight" or "non-retractable" foreskin but was not treated were not classified as phimosis, due to the likelihood that most of these attendances resulted from parental anxiety or uncertainty about the development of the foreskin rather than any pathologic condition in the child. The third type was inadequate circumcision requiring repair or recircumcision. Fourth was postoperative infection after circumcision from birth to 8 years of age by circumcision status. Findings were inconclusive for the first year of life; the adjusted rate of problems experienced was 5.2 penile problems per 100 circumcised boys over the study period, compared with 1.2 penile problems in uncircumcised boys at risk. From ages 1 through 8 years, the rates were 6.5 penile problems per 100 circumcised boys over the study period, compared with 17.2 penile problems per 100 uncircumcised boys."

Comment: Incomplete/Biased/Misleading: Reference 76, which the Task Force is ignoring here, looked at a consecutive sample of 468 boys and found that circumcised boys under 3 years of age were significantly more likely to have a partially or completely covered glans, a reddened meatus, balanitis, or trapped epithelial debris, and less likely to have a fully exposed glans than were circumcised boys of 3 years or older. Among the 238 boys under 3 years, those circumcised were significantly more likely to have non-cosmetic problems, including coronal adhesions, trapped epithelial debris, a reddened meatus, preputial stenosis (phimosis) and balanitis, than were boys with a foreskin. Findings in the circumcised group under 3 years included: fully exposed glans (n = 78, 35.6%), partially covered glans (n = 67, 30.6%), adhesions (25.6%), completely covered glans (20.1%), entrapped desquamated epithelial debris (24.7%), reddened meatus (19.1%), balanitis (15.5%), and preputial stenosis (0.9%). Only two genital examinations in the 36 boys with foreskins revealed pertinent findings. Coronal adhesions develop in circumcised boys at 2-6 months of age and usually resolve by 24 months. The degree of skin covering the glans after neonatal circumcision peaks at 6 months of age. Penile inflammation (balanitis) may be more common in circumcised boys; preputial stenosis (phimosis) affects circumcised and intact boys with equal frequency.[ref 76] A subsequent publication, ignored by the Task Force, using expanded data from the same cohort looking specifically at penile inflammation, found that boys under three years of age with an intact penis had penile inflammation in only 1 out of 43, while 69 of 430 circumcised boys did (OR=8.01, 95%CI=1.31-329.15). For boys three years and older, penile inflammation was much less common and there was no difference based on circumcision status (OR=0.78, 95%CI=0.11-34.45).[Van Howe (Clin Pediatr) 2007] "Uncertainty about the development of the foreskin" is one issue that will go unresolved based on the AAP's neglect in addressing it in their policy statement either because they do not wish it to be discussed or because they lack the knowledge required to discuss it.

Sexual Function and Penile Sexual Sensitivity

Statement 181: "The literature review does not support the belief that male circumcision adversely affects penile sexual function or sensitivity, or sexual satisfaction, regardless of how these factors are defined."

Comment: **Inaccurate, incomplete, completely biased**. The Task Force fails to discuss the anatomy, histology, development, or the function of the foreskin. Briefly, it is a pentalaminar erogenous specialized junctional tissue with a high concentration of fine-touch neuroreceptors. [Taylor et al 1996, Cold & Taylor 1999] It has an important role in protecting the glans, providing sexual pleasure, and preserving the penilocavernosus reflex.[Podnar 2012] This omission is an unconscionable breach of the standard in which reviews of this sort are organized. Any meritorious review or discussion of a procedure is expected to contain at least a cursory discussion of the anatomy and physiology of the body parts affected. The Task Force report does not even provide this.

One study of poor to fair quality found that women who had sexual experience with both circumcised and intact men strongly preferred sex with the intact male for several reasons. [O'Hara & O'Hara 2009] Another study of excellent quality from Denmark found that circumcised men were significantly more likely to report frequent orgasm difficulties, while the female sexual partners of circumcised men were significantly more likely to report incomplete sexual needs fulfillment, significantly more frequent sexual function difficulties, significantly more orgasm difficulties, and significantly more dyspareunia (painful intercourse). [Frisch, Lindholm, & Grønbæk 2011] Two studies have found that the circumcised adult penis is significantly smaller than the intact adult penis.[Richters et al 1995, Fletcher 2013] There are also two studies that found MSM are significantly more likely to be circumcised. In the study from San Francisco, the odds ratio was 1.13 (95%CI=1.10-1.16)[Mor et al 2007] while in the study from Tel Aviv, Israel the odds ratio was 1.57 (95%CI=1.11-2.22).[Mor et al 2012] More study of this association is needed.

Statement 182: "Literature since 1995 includes 2 good-quality randomized controlled trials that evaluated the effect of adult circumcision on sexual satisfaction and sensitivity in Uganda and Kenya, respectively.[126,127]"

Comment: Inaccurate, misleading, incompetent. A review of the questions given to the participants in one of these trials shows that the questions used were vague and unable to demonstrate a difference, even if one existed.[Frisch 2011] It is not surprising that these studies, designed as they were, did not find a difference. More importantly, the questions asked of the participants did not come from a validated survey tool. The lack of a valid measure makes the quality of these trials "unsatisfactory" rather than "good." The results of these trials should raise suspicions because the rates of sexual dysfunction in both of these studies were 3 to 20 times lower than those reported in other countries where studies used validated tools. [refs 129, 130, 133-135, Frisch et al 2011, Ferris et al 2010, Shen et al 2004, Masood et al 2005, Tang & Khoo 2011] Perhaps Kenya and Uganda, given the low rates of sexual dysfunction, should promote this "fact" as part of their tourism campaigns. The Task Force shows its incompetence/bias by not looking carefully at the methods of the study and failing to place the study results in the context of other published studies. The failure to use validated measures, or publish the questions administered to participants, should have signaled that these studies were problematic. Coupled with results that clearly lie outside the range of other published results, the Task Force should have investigated further. Instead, it appears the Task Force unquestioningly accepted these results because they favored circumcision and were from a supposedly randomized controlled trial.

Statement 183: "Among 5000 Ugandan participants, circumcised men reported significantly less pain on intercourse than uncircumcised men.[126]"

Comment: **Incomplete**. Hard to know what to make of these results when the men were given several weeks worth of free pay, a free circumcision (equivalent to three months wages), and free health care for two years. With the strong possibility of undue influence, the participants had

Analysis of 2012 AAP Task Force on Circumcision Report

motivation not to complain and to give the investigators the responses they were seeking: validation that circumcision caused no harm. Also, the reported rates of pain on intercourse were much lower in this study compared to other studies, which makes them either difficult, if not impossible, to interpret, or not credible.

Statement 184: "At 2 years' postcircumcision, sexual satisfaction had increased significantly from baseline measures in the control group (from 98% at baseline to 99.9%); satisfaction levels remained stable among the circumcised men (98.5% at baseline, 98.4% 2 years after the procedure). This study included no measures of time to ejaculation or sensory changes on the penis. In the Kenyan study (which had a nearly identical design and similar results), 64% of circumcised men reported much greater penile sensitivity post-circumcision.[127]"

Comment: **Misleading/Unbelievable/Not credible**. See two previous comments. With sexual satisfaction at 98%, a rate that is the highest recorded ever on the planet, there is very little room for improvement, and any incremental improvement would hardly be noticed. So, why would anyone take the chance and risk altering something that is nearly perfect? The test was too easy. An analogy would be to administer a second-grade math test to sixth graders before and after an intervention. The test would be too easy to document a difference, even if one existed. Educators know that if a test question is correctly answered more than 85% of the time, the question will not provide differential information. Furthermore, there are multiple studies showing a decrease in sexual sensitivity post-circumcision. How is it possible to have an increase in penile sensitivity when the fine-touch nerves have been removed? This result is not even credible or believable as it contradicts what we know about the anatomy.

Statement 185: "At the 2-year follow-up, 55% of circumcised men reported having an easier time reaching orgasm than they had precircumcision, although the findings did not reach statistical significance. The studies' limitation is that the outcomes of interest were subjective, self-reported measures rather than objective measures."

Comment: **Misleading**. Basically they found that circumcision was related to premature ejaculation, but they did not want to state the result in those terms. Circumcision has been associated with premature ejaculation in several other studies.[ref 133, O'Hara & O'Hara 1999, Richardson & Gloomier 2005] Most notably, one study found that circumcised men were almost five times more likely to have premature ejaculation (adjusted OR=4.88, 95%CI=2.35-10.15). [Tang & Khoo 2011] Clearly, this is not a positive outcome.

Statement 186: "Other studies in the area of function, sensation, and satisfaction have been less rigorous in design, and they fail to provide evidence that the circumcised penis has decreased sensitivity compared with the uncircumcised penis. There is both good and fair evidence that no statistically significant differences exist between circumcised and uncircumcised men in terms of sexual sensation and satisfaction.[128–131] Sensation end points in these studies included subjective touch and pain sensation, response to the International Index of Erectile Function, the

Brief Male Sexual Function Inventory, pudendal nerve evoked potentials, and Intravaginal Ejaculatory Latency Times (IELTs)."

Comment: Inaccurate, incomplete, self-contradictory, inconsistent with medical evidence. How can the Task Force state that studies "fail to provide evidence that the circumcised penis has decreased sensitivity compared with the uncircumcised penis," and then note fine-touch sensitivity was decreased in the glans of circumcised males in Statement 187? Three studies have found that the flaccid glans in the circumcised penis has decreased sensitivity to fine-touch using an objective measure. [ref 128, ref 132, ref 136) In one study, the difference was statistically significant when looking at the raw data, but was no longer statistically significant when controlled for age and other medical factors. [ref 128] In another very small study, this difference is shown graphically, but the numbers and whether the difference was statistically significant are not provided in the manuscript.[ref 136] In the largest study of healthy men that provided complete sampling of the penis, the difference was statistically significant for both the raw numbers and after controlling for a variety of demographic factors.[ref 132] Reference 129 only assessed intravaginal ejaculation latency time, which may only be tangentially related to sexual sensation or satisfaction. By asserting that the evidence from these negative studies is "good" without providing a power analysis, the Task Force is expecting the reader to blindly trust their judgments. Such trust needs to be earned. This type of misappropriation of citations is consistent with the lack of scholastic rigor demonstrated throughout the report.

Several small studies have surveyed adult men with medical indications for circumcision to determine differences in sexual response following surgery. Although surgery was intended to be beneficial, a substantial number of these men failed to improve or worsened. They reported increases in erectile dysfunction, loss of sensitivity, and problems with intromission.[Fink, Carson, & DeVellis 2002, Coursey et al 2001, Collins et al 2002, Shen et al 2004] Only two studies of this type did not share these findings and these are the studies cited by the Task Force. [ref 130, ref 131] Both of these studies were from Turkey. Why did the Task Force include these references and not the other studies similar in design but with a different outcome? The results of these studies are limited by the short duration of follow-up and by expectation bias. Patients are susceptible to expectation/confirmation bias that surgery used to correct a problem will, in fact, correct that problem. Consequently, the men who seek circumcision are predisposed to reporting a favorable outcome.

<u>Update</u>: At least four studies have been published since the report's release in 2012. All have found that circumcision significantly reduces sexual sensation, sexual satisfaction and it interferes with sexual functioning.[Frisch et al 2011, Podnar 2012, Bronselaer et al 2013, Dias et al 2014]

Statement 187: "There is fair evidence that men circumcised as adults demonstrate a higher threshold for light touch sensitivity with a static monofilament compared with uncircumcised men; these findings failed to attain statistical significance for most locations on the penis,

however, and it is unclear that sensitivity to static monofilament (as opposed to dynamic stimulus) has any relevance to sexual satisfaction.[132]"

Comment: **Inaccurate interpretation of study findings, misleading, incomplete**. Reference 132 found that the glans of the circumcised penis was significantly less sensitive to fine touch than the glans of the intact penis. The study did *not* evaluate men circumcised as adults. Nearly all of the circumcised men in the study were circumcised as infants. The end point of the study was not the difference in sensitivity between individual locations on the penis, but the overall sensitivity of the penis, which is why the data was put into a marginal mixed model. The Task Force, as well as some of the study's critics, failed to grasp that the study was designed to measure the overall impact of circumcision on the sensitivity of the glans to fine touch. Their statement indicates that the Task Force was more influenced by the inappropriate and unwarranted criticisms of the study than if they had read and understood the methodology of the study. The study also found that the frenulum and ridged band portions of the foreskin were the most sensitive on the intact penis, while the circumcision scar was the most sensitive portion of the circumcised penis. It is not clear why this is considered "fair" rather than "good" evidence.

There are three other studies that used objective physiologic measures of the penis. One underpowered study (20 in each group, did not evaluate the foreskin, but found no differences between circumcised and intact men. In figure 2 of this study, it appears that the glans in the intact penis is more sensitive to fine touch than the circumcised penis at baseline. The article does not provide the data for this.[ref 136] This finding is consistent with the finding in Reference 132. A second study measured fine-pressure thresholds on three locations and found intact men were significantly more sensitive on the glans, but the differences were no longer statistically significant when adjusted for age, diabetes mellitus, and hypertension.[ref 128] A third study found decreased vibratory sensation in the glans following circumcision.[Yang et al 2008]

Statement 188: "There is fair evidence from a cross-sectional study of Korean men of decreased masturbatory pleasure after adult circumcision.[133]"

Comment: **Incomplete**. Reference 133 also found circumcision was associated with premature ejaculation.

Sexual Function

Statement 189: "There is both good and fair evidence that sexual function is not adversely affected in circumcised men compared with uncircumcised men.[131,134–136] There is fair evidence that no significant difference exists between circumcised and uncircumcised men in terms of sexual function, as assessed by using the IELT.[129]

Limitations to consider with respect to this issue include the timing of IELT studies after circumcision, because studies of sexual function at 12 weeks postcircumcision by using IELT

measures may not accurately reflect sexual function at a later period. Also, the self-report of circumcision status may impact study validity. This could be in an unpredictable direction, although it is most likely that the effect would be to cause an underestimation of the association. Other biases include participants' ages and any coexisting medical conditions."

Comment: Incomplete review of the medical evidence, statement not supported by citation, outdated, inaccurate. The Task Force fails to discuss how the foreskin contributes to sexual function. Intromission with a circumcised penis has been likened to thrusting the foot into a sock held open at the top. By contrast with the intact counterpart having a foreskin, it is like slipping the foot into a sock that had previously been rolled up.[Morgan 1965, Morgan 1993] Consequently, during coitus the intact phallus penetrates smoothly with the prepuce retracting as the glans advances; [Taves 2002] however, when the circumcised penis is introduced, friction and chafing frequently develop.[Morgan 1993, Lubcheco 1980, Taves 2002, O'Hara & O'Hara 1999, Warren & Bigelow 1994] The double-surfaced prepuce provides the skin necessary to accommodate the expanded erect penis and allows the shaft and glans to slide freely, smoothly, and pleasurably beneath the penile skin system, which includes the prepuce. This facilitates smooth, gentle movement between the mucosal surfaces of the two partners during intercourse. The prepuce enables the penis to slip in and out of the vagina non-abrasively inside its own sheath of self-lubricating, movable skin. The female is stimulated by moving pressure rather than by the friction provided by a penis with the prepuce missing. [Lakshmanan & Prakash 1980] Circumcision tightens the penile skin and destroys the gliding action, causing difficult insertion, [Shen et al 2004] abrasive intercourse, [Warren & Bigelow 1994] and an increased need for artificial lubrication.[O'Hara & O'Hara 1999] Some have even bizarrely speculated that male circumcision was implemented purposely to displace vaginal secretions and semen as part of a semen competition strategy.[Gallup & Burch 2004, Bowman 2010]

The Task Force did not include studies of men circumcised as adults for medical reasons who compared their sexual function before and after the procedure.[Fink et al 2002, Collins et al 2002, Coursey et al 2001] While the follow-up of these studies was not long enough for the desensitizing effect of circumcision to affect the glans and the studies are extremely susceptible to confirmation bias, each of these three studies saw a substantial percentage with either no improvement (which may have been expected following correction of the medical condition) or worsening of function. Of the four studies with this study design available for review, the Task Force cited the study that presented circumcision in the most favorable light.[ref 131] A survey study of 139 women who had sexual experience with intact and circumcision status of the male sexual partner markedly impacted the sexual experience of the female partner, with an intact partner being preferred in every category. This was essentially a pilot study of fair quality, it appeared in a first line journal and should not have been excluded. The findings of this study have been subsequently confirmed in a representative national survey.[Frisch et al 2011]

The Task Force only cited one study that assessed premature ejaculation[ref 129] while ignoring the nine other studies that were available in the medical literature at the time the report was

Analysis of 2012 AAP Task Force on Circumcision Report

published.[refs 127, 134, 135, Frisch et al 2011, Son et al 2010, Tang & Khoo 2011, Ferris 2010, Massod et al 2005, O'Hara & O'Hara 1999] A thorough review of the medical literature would have found some studies showing a significant increase in the prevalence of premature ejaculation in circumcised men and some studies showing no difference. Because they did not perform a complete review of the medical literature their statement is inaccurate. The Task Force could have also looked at the geographic data and noted that the prevalence of premature ejaculation(32%[ref 135]) in the United States, where the majority of men are circumcised, is far greater than in similarly situated countries in Europe (England (11.15%),[Dunn et al 1998] France (15%),[Wespes et al 2012] Sweden (9%),[Fugi-Meyer & Sjogren Fugi-Meyer 1999] Denmark (14%),[Solstad & Hertoft] Italy(21%),[Basile Fasolo et al 2005] Netherlands(13%) [Blanker et al 2001]), where male circumcision is rarely performed.

The statements regarding the impact of misclassification reflect an ignorance of how misclassification bias works. Misclassification bias is possible when participants in a study are classified incorrectly. The classification of interest in most of the studies that were evaluated by the Task Force was circumcision status. This can be determined in primarily two ways: physical examination and self-report of the participant. Multiple studies have demonstrated that men are commonly (sensitivity as low as 57%) misclassified in studies that rely on self-report.[refs 8, 51, 69, Lajois et al 2005, Parker et al 1983, Brinton et al 1989, Schlossberger et al 1992] If the misclassification happens randomly, the estimate of the association will tend toward the null hypothesis. The statement by the Task Force that "it is most likely that the effect would be to cause an underestimation of the association," is misleading. It assumes that there is an association to be found, when there may not be an association. It does not underestimate the association, it pulls the estimate towards the null hypothesis. This is the impact if the misclassification is non-differential (random and not associated with other factors of interest), but it is not known whether most of the studies that relied on self-report of circumcision status had non-differential misclassification. It is quite likely that the misclassification was differential, meaning those men who incorrectly identified their circumcision status differed in meaningful ways from those who were able to correctly identify their circumcision status. If this is the case, then the misclassification can differentially bias the estimates of association.[Mertens 1993] It is disingenuous for the Task Force to raise the possibility of misclassification bias in this context as an attempt to undermine the validity of the studies on this topic when there is growing evidence that circumcision negatively impacts sexual function, yet the validity of studies that support circumcision and relied on participant self-report to determine circumcision status are not questioned. For the Task Force, the direction of results consistently trumped methodology.

Reference 136 did not assess sexual function but rather physiological measures. If this reference is used to support this statement, then References 128 and 132 should also be included, but reference Reference 132 undermines this claim.

<u>Update</u>: See Statement 186. Since publication, three studies have looked at the role of circumcision in premature ejaculation. [Shaeer 2013, Alp et al 2014, Dias et al 2013] When all of the studies are combined in a meta-analysis, there is a strong, but non-significant, trend toward

Analysis of 2012 AAP Task Force on Circumcision Report

intact men having a lower prevalence of premature ejaculation. The study by Krieger et al, [ref 127] a study of poor quality, is a clear outlier.

Statement 190: "The analgesics used for newborn circumcision include nonpharmacologic and pharmacologic (topical and nerve blocks) techniques. The Task Force's review included nonnutritive sucking, a pacifier dipped in sucrose, acetaminophen, topical 4% lidocaine (ie, LMX4 cream), a eutectic mixture of lidocaine-prilocaine local anesthetic (EMLA), subcutaneous ring block, and the dorsal penile nerve block (DPNB). These methods, which reduce the pain and stress of newborn circumcision, are representative of the principles discussed in the AAP Policy Statement on Prevention and Management of Pain in the Neonate, which was updated in 2006. [137,138]"

Comment: Accurate.

Statement 191: "There are no evidence-based recommendations that state there is persistent pain that must be treated after the local pre-procedure anesthetic wears off."

Comment: Unsubstantiated, inconsistent with medical evidence and rational medical thought, misleading. No citation is given. There is ample evidence that behavior and sleep changes persist for at least a week following infant circumcision.[Brackbill 1975, Emde et al 1971, Anders & Chalemian 1974, Marshall et al 1980, Marshall et al 1982, Dixon et al 1984] This would suggest that there is post procedure pain. There is also ample evidence that postprocedure pain in circumcision requires treatment for those circumcised later in life otherwise there would not be a plethora of studies on the topic.[Holthusen et al 1994, Ramboatiana et al 1990, Lau 1984, Bacon 1977, Bramwell et al 1982, Lunn 1979, Chambers1994, Martin 1982, Wong 1986, Nielsen et al 1988, Martinez Telleria et al 1997, Lee & Sanders 2000, Bogaert et al 2005, Naja et al 2011, George et al 2011, Beyaz 2011, Micha et al 2009] While there is no "evidence-based statement" it does not mean there is no evidence or that it exempts the Task Force from evaluating the evidence by looking at the neurologic pain pathways in place at birth and looking at how older children and adults respond post-operatively. It is unconscionable for a medical organization interested in the health and well-being of children to deny the existence of pain after the amputation of a body part. Clearly, all human beings will suffer from pain and discomfort following a surgical procedure, which is demonstrated quite effectively in older children and adults undergoing the same surgery.

Statement 192: "Analgesia is safe and effective in reducing the procedural pain associated with newborn circumcision, as indicated by changes in heart rate, oxygen saturation, facial action, crying, and other measures.[139–145]"

Comment: **Inconsistent with other AAP policy**. The analgesia given for infant circumcision is inadequate. The changes in vital signs and cortisol levels during circumcisions performed with topical and local anesthetics indicate that the procedure is still painful and adequate pain relief is not being delivered. While these agents may reduce the procedural pain, the procedure is still

notably painful and stressful. AAP policy is that infants should be afforded the same pain relief that is given to older children and adults.[Poland et al 1987, Committee on Fetus and Newborn, 2000] Older children and adults are given general and regional anesthesia. Therefore, adequate analgesia should be provided when newborn circumcision is performed. It must also be noted that many of the studies looking at the effectiveness of topical and local anesthetics for infant circumcision used control groups for whom no anesthetic was given. This occurred after the DPNB was shown to reduce some of the indirect measures of pain, making these studies in violation of the Helsinki Declaration for treatment of human subjects.[Van Howe & Svoboda 2008] Furthermore, if general or regional anesthesia is contraindicated in newborns, so too should other types of anesthesia be contraindicated for an unnecessary cosmetic surgery whose risks and complications have not been fully studied. EMLA cream is not only ineffective, but potentially dangerous (see Statement 201).

Statement 193: "Topical 4% lidocaine, DPNB, and a subcutaneous ring block are all effective options, although the latter may provide the most effective analgesia."

Comment: **Misleading**. None of the anesthetic options for infant circumcision provide adequate anesthesia, so why would they be considered "effective?"

Statement 194: "In addition there is good evidence that infants circumcised without analgesia exhibit a stronger behavioral pain response to subsequent routine immunization at 4 to 6 months of age, compared with both infants circumcised with analgesia and with uncircumcised infants. [145]"

Comment: **Misleading**. While those who received an anesthetic during infant circumcision had less of a pain response than those who did not receive an anesthetic, they still had a stronger pain response than the boys who were not circumcised.[ref 145] This finding is important because it is strong evidence that infant circumcision has a permanent impact on the brain and how painful stimuli are processed.[ref 145, Taddio et al 1995]

Statement 195: "The literature search did not produce any reports of local anesthetic toxicity, such as seizures or cardiovascular instability, among the newborns receiving either local anesthetic injections or topical applications (ie, topical 4% lidocaine)."

Comment: Unclear. There have been multiple reports of toxicity from EMLA application as noted below.[ref 156-158] There are several case reports of complications from using a local anesthetic that contained epinephrine.[Sara & Lowry 1985, Berens & Pontus 1990, Wetchler & Moore 1955, Smith et al 1994] This is another example that the literature search undertaken by the Task Force was incomplete.

Statement 196: "There is good evidence that oral sucrose and oral analgesics are not different from placebo or environmental modification in their ability to control pain.[141,142,144] There is good evidence that a more physiologic positioning of the infant in a padded environment may

decrease distress during the procedure.[146] There is fair evidence that sucrose on a pacifier has been demonstrated to be more effective than water alone for decreasing crying during circumcision.[147–149] Non-pharmacologic techniques alone are insufficient to prevent procedural pain, however. Positioning and a sucrose pacifier should be used as analgesic adjuncts to improve infant comfort during circumcision but are not recommended as the sole method of analgesia."

Comment: **Misleading**. This statement fails to make the distinction between pain and the secondary measures that are believed to be the result of pain. Crying duration is weakly (compared to other secondary measures) associated with noxious stimuli and can be redirected with oral stimuli. If crying is reduced through redirection, it does not mean the pain is reduced. This is why experts on neonatal pain recommend that pain should be assessed using multiple modalities including vital signs, oxygenation, vagal tone, humoral response (cortisol levels), behavioral response, and pain-specific brain activity.[Gunnar et al 1995, Slater et al 2010] The ethical problems of using placebo controls has been addressed.[Van Howe & Svoboda 2008]

Statement 197: "There is good evidence that topical anesthesia with lidocaine-prilocaine (which contains 2.5% lidocaine and 2.5% prilocaine) or 4% lidocaine is superior to no anesthesia in preventing pain during male circumcision.[150]"

Comment: **Incomplete**. While being superior to no anesthetic, it is just barely so. Most practitioners do not use this because better options are available and it is imperceptibly better than placebo.[ref 148] Also, this trial was unethical because it used placebo controls when it was known that DPNB was effective.[Van Howe & Svoboda 2008] The Task Force fails to mention that there were two studies using topical lidocaine-procaine as the only anesthetic for circumcision in adult men; both studies were terminated after only a few patients because the topical agent failed in all cases with the procedure being excruciatingly painful when this anesthetic was used.[Laffon et al 1998, Siddique et al 1997]

Statement 198: "There is good evidence from a prospective cohort study that lidocaine-prilocaine cream attenuates the pain response to circumcision (as measured by using heart rate, oxygen saturation, facial actions, and time and characteristics of crying) when applied 60 to 90 minutes before the procedure.[150,151] There is fair evidence from an RCT that lidocaine-prilocaine cream attenuates the pain response to circumcision, although it was less effective in doing so than DPNB or ring block.[152] There is good evidence that topical 4% lidocaine is as effective as lidocaine-prilocaine at preventing pain.[140,153] Topical 4% lidocaine has the advantage of having a faster onset of action (2 g applied 30 minutes before circumcision, compared with 1 to 2 hours before circumcision for lidocaine-prilocaine). Both topical preparations require coverage with plastic wrap to keep the cream in place. Topical 4% lidocaine is the preferred topical local anesthetic (over lidocaine-prilocaine) because there is no risk of methemoglobinemia."

Comment: **Accurate**. Some of these trials have the ethical problems discussed above. Do any Task Force members wish to have a portion of their genitals sliced off with only topical cream

Analysis of 2012 AAP Task Force on Circumcision Report

used for anesthesia? Doubtful. This is done to infants only because they cannot effectively fight back.

Statement 199: "The most common complications reported with analgesic techniques were an 8% to 14% incidence of erythema, swelling, and blistering associated with topical analgesia. [142,150,153,154] There is fair evidence that adverse effects of topical anesthetic creams are infrequent and include only either minor skin reactions (ie, erythema, swelling) or, more rarely, blistering (especially in low birth weight infants).[154] For this reason, penile nerve block techniques should be chosen for low birth weight infants. There is good and fair evidence that both reactions are less common with 4% lidocaine than with lidocaine-prilocaine cream. [142,150,153–155]"

Comment: Accurate. Blistering certainly causes post-op pain.

Statement 200: "There is a theoretical risk of methemoglobinemia with lidocaine-prilocaine. [152]"

Comment: **Misleading, internally inconsistent**. The risk is more than theoretical, it is real, as the many case reports in the medical literature attest to. How can the risk be theoretical when there are real cases? This contradicts the next statement.

Statement 201: "However, when methemoglobin has been measured after lidocaine-prilocaine application, the level, although elevated, was not clinically significant.[150] Nevertheless, there have been isolated case reports of clinically significant methemoglobinemia involving prolonged application time or use in premature infants.[156,157,158]"

Comment: Accurate. Additional cases have been reported.[Cade & Shollenberger 2003, Elsner & Dummer 1997, Mandel 1989, Tse et al 1995, Özbek& Sarikayalar 1993, Prunes et al 1997, Ford & Agnew 1972, Jakobson & Nilsson 1985, Boran et al 2008, Ozdogan et al 2010, Akbayram et al 2012, Arda et al 2000] Did they do an inadequate literature search that only identified the three reports, or did they limit the number of citations to minimize the frequency of the complications? Given that this was an online publication, there was no reason to limit the number of citations.

Statement 202: "Most commonly, DPNB consists of injections of 0.4 mL of 1% lidocaine without epinephrine on both sides of the base of the penis. Systemic lidocaine levels obtained with use of this technique reached peak concentrations at 60 minutes after injection and were well below toxic ranges.[159]"

There is good evidence that DPNB is effective in reducing the behavioral and physiologic indicators of pain caused by circumcision, regardless of the device used.[144] There is good evidence that DPNB is superior to lidocaine-prilocaine in relieving pain during and after circumcision in newborns.[142,160–162] One good-quality prospective cohort study of 491 new-

born circumcisions measured complications of DPNB analgesia; it reported an 11% incidence of bruising and a 0.2% incidence of hematoma, none of which required any change in management. [163] Another good-quality, blinded, randomized controlled trial found a 43% incidence of small hematomas in preterm and term newborns circumcised by using DPNB.[142]"

Comment: **Incomplete, inaccurate**. Need to emphasize that DPNB does not provide adequate anesthesia because in many cases it only anesthetizes the *dorsum* of the penis, while the most senstitive structures of the penis are on the ventral side of the penis.[Keneko & Bradley 1987] That is why it is called Dorsal Penile Nerve Block. If the Task Force had looked at the anatomy of the foreskin they would be aware of this. DPNB has been reported to have high failure rates. In one study in which DPNB was used, 60% of the infants had pain or discomfort associated with the procedure that was judged to be excessive.[Taeush et al 2002] Some researchers have recommended additional injections of lidocaine at the base of the penis on its ventral aspect for this reason.[ref 175, ref 176, Serour et al 1994, Kelâmi 1989, Wakefield & Elewa 1995, Stav et al 1995]

Statement 203: "Two studies with fair evidence found that the subcutaneous circumferential ring block (0.8 mL of 1% lidocaine without epinephrine injected at the base or midshaft of the penis) is effective in mitigating pain and its consequences during circumcision of newborns.[164]"

Comment: **Incomplete**. Besides the injections being painful, what does the Task Force mean by "consequences"? Does this refer to the disturbances in sleep and behavior (see Statement 191) or the changes in response to subsequent painful stimuli?[ref 145, Taddio et al 1995] These consequences were not assessed following the use of ring block. This trial was unethical because it used placebo controls when it was known that DPNB was the standard of care.

Statement 204: "One study presented fair evidence that the ring block was superior to using no anesthesia but found a 5% failure rate with the technique (1 in 20 ring block infants had heart rate and behavioral pain scores that were above the control mean during at least 50% of the measured intervals, while 19 of 20 had heart rate and pain scores less than the control mean). There were no hematomas in the infants receiving ring blocks. A second ring block study had fair evidence that the method was superior to either DPNB or lidocaine-prilocaine cream for pain relief in newborn circumcision, as the ring block seemed to prevent crying and increases in heart rate during all phases of the circumcision, with less crying and lower heart rates during foreskin separation and incision than seen with DPNB or lidocaine-prilocaine.[152] No complications have been reported in the use of this simple and highly effective technique."

Comment: **Misleading**. The lack of reported complications, does not mean that there are not any. It depends on how complications are defined and how long the participants are followed. Lidocaine and methemoglobin levels should be measured in a study setting. Lidocaine has numerous common adverse effects, some of which would require continuous ECG monitoring to detect, and many would be extremely difficult to detect in newborns (confusion, lethargy, hallucinations, dizziness, etc.)

Analgesia and Anesthesia for a Circumcision After the Newborn Period

Statement 205: "In the United States, after the newborn period, general anesthesia is used during male circumcision because the surgical procedure takes longer and involves hemostasis and the suturing of skin edges."

Comment: **Inaccurate**. While these technical elements may be factors, the primary reason general anesthesia is used is because topical and local anesthetics are not effective and do not provide adequate anesthesia. It is also much easier to restrain an older child when they are under general anesthesia. There were two trials in which EMLA cream alone was tried for the circumcision of older patients. Neither study could be completed because the cream was ineffective.[Siddique et al 1997, Laffon et al 1998] General comment: Why is there such a long section on analgesia and anesthesia for circumcision after the newborn period when other key topics such as ethics, anatomy, and physiology were either excluded or glossed over? Why does this section go into more detail than the section on analgesia and anesthesia for newborn circumcision? Is this because the Task Force is trying to scare physicians and parents into thinking that circumcision after the newborn period is fraught with danger?

Statement 206: "Use of adjuvant local anesthetic techniques in addition to general anesthesia provides longer-lasting postoperative analgesia, minimizes the need for intraoperative or postoperative opioid administration, reduces adverse postoperative events such as nausea and vomiting, and decreases recovery time. Long-lasting analgesia is achieved with either penile nerve block, by using any of the methods mentioned earlier, or caudal epidural analgesia in infants and children up to 3 years of age."

Comment: Accurate.

Statement 207: "General anesthesia carries a low risk of mortality (1 death per 400 000 instances of general anesthesia). The risk of adverse events (especially respiratory events) during general anesthesia remains higher in infants under 1 year of age.[165] These risks are minimized when the procedure is performed in infants in their optimal state of health (no active reactive airway disease or upper respiratory infection) and in a facility familiar with the anesthesia care of infants.[166]"

Comment: Accurate.

Statement 208: "Additional concerns associated with surgical circumcision in older infants include time lost by parents and patients from work and/or school."

Comment: **Random flight of ideas, irrelevant**. Not sure what this has to do with the anesthesia discussion, but it is likely another attempt to scare parents and physicians into circumcising as a newborn. This statement plays into the myth that the recovery period is shorter following

neonatal circumcision. There is no scientific claim to support this presumption. It also reflects the presumptions on the part of the Task Force that the well-being of infants is not as important as that of older children and adults.[Alderson 1993] From a neurodevelopment standpoint, the immediate postnatal period is crucial.

Statement 209: "Caudal block (CB) with bupivacaine is an anesthetic technique used for postoperative analgesia for circumcision in infants and older children up to 3 years of age, as an alternative to ring block and DPNB techniques. There is good and fair evidence that there is a longer time to first postoperative urination after CB without adverse clinical consequences. [167,168] There is good evidence for a high incidence of mild postoperative motor block and delay in walking after the CB procedure (21% to 44%) in older children.[167,169,170] Caudal analgesia may be less available in facilities that do not treat many pediatric patients."

Comment: **Incomplete**. Since the studies in older children indicate that caudal block is superior to DPNB and that caudal blocks can be given to infants, why not consider a caudal block for infant circumcision? Caudal block is often used to help with postoperative pain. (See Statement 191)

Statement 210: "[Circumcision on older boys] The reported failure rate of DPNB is 1% to 10%. [171–175] When DPNB is used without general anesthesia in boys 3 to 5 years of age, the technique has a failure rate of 15%; for boys aged 6 and older, the failure rate is 1.5%.[175] There is good and fair evidence that incidence of hematoma with DPNB ranges from 0.001% to 24%; several studies report rates of approximately 6%.[174–177] One study with fair evidence reports a 0.001% rate of "improper needle position with bleeding" and a similar number of "medication errors."[176] Studies with good and fair evidence report a 12% to 83% rate of edema in the area of injection of the local anesthetic after DPNB.[174,175,177]"

Comment: **Incomplete, misleading**. DPNB is often used to help with postoperative pain. The failure rate of DPNB in neonatal circumcision is between 30% and 60%,[Taeush et al 2002] so if the Task Force is trying to depict anesthesia for circumcision in older boys as difficult and onerous, they need to remind the reader that adequate anesthesia is not available for circumcision in the newborn period.

Statement 211: "[Circumcision on older boys] There is good evidence for the reported 8% failure rate using the ring block.[168] In children, edema and distortion of tissue layers after the ring block make surgery more difficult, compared with using a CB to prevent postoperative pain. [178]"

Comment: Accurate.

Statement 212: "Comparison of Methods [Circumcision on older boys] DPNB, subcutaneous ring block, and CB techniques may be used in conjunction with general anesthesia depending on the age of the child and are also used to provide post-circumcision analgesia. There is good

Analysis of 2012 AAP Task Force on Circumcision Report

evidence that there is no difference in the quality of postoperative analgesia or parent satisfaction between DPNB and CB using bupivacaine.[169] A comparison of CB with or without a subcutaneous ring block with bupivacaine showed good evidence that CB with a subcutaneous ring block had significantly longer duration of postoperative analgesia.[168] A technique describing ultrasound guidance for correct needle placement for DPNB in children under general anesthesia describes lower pain scores in the first postoperative hour and a longer interval until rescue analgesia was required.[179,180]"

Comment: Accurate. If older children deserve this extensive pain control during and after circumcision, then infants do too.

Statement 213: "The true incidence of complications after newborn circumcision is unknown, in part due to differing definitions of "complication" and differing standards for determining the timing of when a complication has occurred (ie, early or late). Adding to the confusion is the comingling of "early" complications, such as bleeding or infection, with "late" complications such as adhesions and meatal stenosis."

Comment: **Incomplete**. If it is difficult, if not impossible, to assess the total impact of the complications, then how can the Task Force come to the conclusion that the benefits outweigh the risks? It appears that the Task Force accomplished what is mathematically impossible.

<u>Update</u>: In a subsequent publication the Task Force backtracked and stated that they "felt" the benefits outweighed the risks.[AAP Task Force (JME) 2013] The Canadian Paediatric Society reached a different conclusion.[Sorokan et al 2015]

Statement 214: "Also, complication rates after an in-hospital procedure with trained personnel may be far different from those of the developing world and/or by untrained ritual providers. For the purposes of this document, complications are grouped in terms of the timing of the procedure. (Citations for the following statements below are provided in the section after this summary.)"

Comment: **Unsubstantiated**, **irrelevant**. No citation given either here or later in the manuscript to support this claim.

Statement 215: "Significant acute complications are rare, occurring in approximately 1 in 500 newborn male circumcisions."

Comment: **Unsubstantiated**. No citation given. The citation that supports this number appears in a study by Gee and Ansell [1976], which is not cited in the report.

Statement 216: "Acute complications are usually minor and most commonly involve bleeding, infection, or an imperfect amount of tissue removed."

Comment: **Unclear**. What is meant by "minor"? What is an "imperfect amount of tissue"? Bleeding and infection complications have been known to lead to death. But these would be found in case reports, for the most part, which the Task Force chose to ignore.

Statement 217: "Late complications do occur, most commonly adhesions, skin bridges, and meatal stenosis."

Comment: **Incomplete** . Late complications occur with much higher frequency than acute complications. Adhesions following infant circumcision occur in 25.5% of boys under three years of age. Most resolve spontaneously. Skin bridges are seen in 4.1%.[ref 76] Meatal stenosis is seen primarily after the third birthday with a range from 5% to 20%. Many of these require a meatotomy.[ref 76, Van Howe 2006, Griffiths, Atwell, & Freeman 1985, Stenram, Malmfors, & Okmian 1986, Persad et al 1995, Joudi, Fathi, & Hiradfar 2011, Fletcher 2013] Most late complications are not known because there are no studies looking for, or at, long-term complications. There are no studies specifically evaluating males for PTSD and other psychologic disorders. Sexual function has been looked at in a few studies. This whole issue of complications caused by circumcision is wide-open for research. Before a procedure should become mainstream, it needs a thorough study of its risks, harms and complications. Some have suggested that if infant circumcision were a new procedure seeking approval and certification, it would be rejected because a careful examination of the risks would stand in the way.[Gollaher 2000]

Statement 218: "There are 2 schools of thought regarding the cause of penile adhesions, which are common after circumcision. One is that fine adhesions represent incomplete lysis of physiologic adhesions at the time of circumcision; the other is that the fine adhesions occur because of raw serosa surfaces."

Comment: **Inaccurate**. This controversy has been resolved. The adhesions occur following circumcision because of raw serosa surface. A longitudinal study found that most children who developed adhesions were adhesion free in the weeks following birth.[ref 76, Van Howe 2001]

Statement 219: "It is unknown how often these late complications require surgical repair; this area requires further study."

Comment: **Inaccurate**. The rate of skin bridges is 4.1%. Approximately 1% of all neonatal circumcisions will require surgical repair.[ref 76] The meatal stenosis rate is known (between 5% and 20%) with the majority of these cases requiring meatotomy.

Statement 220: "In general, the specific technique used does not afford a significant difference in risk of complications. However, boys undergoing circumcisions in medical facilities in industrialized settings performed by trained practitioners have fewer complications than boys in nonindustrialized nations who have circumcisions performed by poorly trained (or untrained) practitioners in nonmedical surroundings."

Comment: **Inconsequential, unsubstantiated**. Like the STD and HIV studies, complication rates documented in Africa do not apply to the United States. No references given. This is an important topic that needs documentation and further study. While the overall rate of complications may be similar between the specific techniques, there are differences in the types of complications seen. For example, Gomco clamps have more bleeding than the Plastibell, while the Plastibell has more infections than the Gomco.[Gee & Ansell 1976]

Statement 221: "If circumcision is performed, it is imperative that those providing the service have adequate training in the method used and resources for and practice of adequate analgesia and infection control."

Comment: **Inconsistent with AAP policy**. Since adequate analgesia is not available in the newborn period, it should be delayed until adequate analgesia can be provided.

Statement 222: "Contraindications to newborn circumcision include significantly premature infants, those with blood dyscrasias, individuals who have a family history of bleeding disorders, and those who have congenital abnormalities such as hypospadias, congenital chordee, or deficient shaft skin such as penoscrotal fusion or congenital buried penis."

Comment: **Misleading**. Since there are no acute medical indications for newborn circumcision, the lack of an indication is a contraindication.

Statement 223: "In addition, before performing newborn male circumcision, the clinician should confirm that vitamin K has been administered, in accordance with standard practice of newborn care.[181]"

Comment: **Incomplete**. In a study looking at the efficacy of vitamin K to prevent bleeding, the overall rate of excess bleeding following circumcision was 9.9%. For those who were given vitamin K, the rate of excessive bleeding was 8.9%; for those who were not given vitamin K, the excessive bleeding rate was 11.0%.[Sutherland et al 1967]

Statement 224: "Two large US hospital-based studies with good evidence estimate the risk of significant acute circumcision complications in the United States to be between 0.19% and 0.22%.[121,123] Bleeding was the most common complication (0.08% to 0.18%), followed by infection (0.06%) and penile injury (0.04%)."

Comment: **Misleading**. References 121 and 123 relied on databases as their source of information. This source of information will yield a complication rate that is ten times lower than complication rates obtained from chart reviews.[ref 184, ref185] Because of the short-comings of using a database that gleans information from the facesheet of the medical record, this data is only adequate under the circumstances; the quality of these studies is "fair." Just because these

databases included a large number of people does not mean the data is informative. There is no guarantee that a large study is a "good" study.

Statement 225: "For comparison, an audit of 33 921 tonsillectomies found an incidence of hemorrhage of 1.9% among children aged 0 to 4 years.[182]"

Comment: Accurate, irrelevant.

Statement 226: "An Israeli prospective cohort study with fair evidence examined 19 478 male infants born in 2001 who were circumcised primarily by trained, ritual providers in nonmedical settings, and reported similarly low complication rates. The overall complication rate was 0.34%, including bleeding in 0.08% and infection in 0.01%.[183] Approximately one-third of the identified complications were immediate (ie, bleeding, infection, penile injury), whereas two-thirds occurred later (ie, excess foreskin, penile torsion, shortage of skin, phimosis, inclusion cyst)."

Comment: **Misleading**. With 19,478 male infants, and no statement of how this population was assessed for complications, it is safe to say there was not a chart review performed. In this sized population, the complication rate is likely underestimated by a factor of ten or more. This is a "fair" study.

Statement 227: "There is fair evidence of a more frequent complication rate of 3.1% in a study based on abstraction of 1951 hospital medical (rather than billing) records on newborn circumcision in Atlanta.[184] In this study, complications were found to be much more common, with bleeding occurring in 2.1%, although most reports of bleeding were mild in nature."

Comment: **Misleading**. This study was an actual chart review, which is a more accurate way of discovering complications than the previous studies mentioned. It is not clear why the database studies were considered "good" evidence and this study was considered "fair" evidence, when this type of study is more likely to generate an accurate estimate. The pattern seems to be that if a study agrees with the committee's circumcision agenda it gets a better rating than if the study does not agree with their circumcision agenda. This study is a "good" study.

Statement 228: "Likewise, a review with fair evidence of 1000 newborn circumcisions by using the Gomco clamp in a hospital setting in Saudi Arabia found an overall complication rate of 1.9%.[185] Bleeding occurred in 0.6%, infection in 0.4%, and redundant prepuce in 0.3%."

Comment: **Misleading**. As another chart review, this should be a "good" study rather than a "fair study.

Statement 229: "Late complications of newborn circumcision include excessive residual skin (incomplete circumcision), excessive skin removal, adhesions (natural and vascularized skin bridges), meatal stenosis, phimosis, and epithelial inclusion cysts. These complications are

considered "late," as opposed to "acute" (or immediate) complications such as bleeding or infection, which may still present during infancy but not during the immediate postprocedural time frame."

Comment: Accurate. Although, there is no standard guideline available to determine what is a "complete or incomplete" circumcision. What many would consider a "complete" circumcision would likely leave insufficient skin for a comfortable erection as an adult.

Statement 230: "In 1 outpatient-based study of 214 boys with poor evidence, the complications seen included adhesions (observed in 55 boys [25.6%]), redundant residual prepuce (44 boys [20.1%]), balanitis (34 boys [15.5%]), skin bridge (9 boys [4.1%]), and meatal stenosis (1 boy [0.5%]).[76]"

Comment: Misleading, inaccurate, incomplete, incompetent. Unclear why this was categorized as "poor" it should be "fair". This is consistent with the Task Force's pattern of contrary evidence regarding circumcision being downgraded. Reference 76 is only partially cited here in that only data from boys under three years of age are cited. After age three is when meatal stenosis typically presents itself clinically. This is the most common complication following circumcision, yet this report tries to ignore it. In the initial publication, Reference 76 found the incidence of meatal stenosis to be 5.6% in those three years and older. Most of these patients required a meatotomy. As this cohort was followed over time, 24 of the 329 Tanner I boys three years and older were diagnosed with meatal stenosis (7.29%). No meatal stenosis was seen in 91 boys with an intact penis.[Van Howe 2006] The incidence of meatal stenosis following circumcision has been reported at 2.8% (requiring meatotomy),[Griffiths, Atwell, & Freeman 1985] 11% (requiring meatotomy), [Stenram, Malmfors, & Okmian 1986] 7.9%, [Persad et al 1995] and 20.4%.[Joudi, Fathi, & Hiradfar 2011] It has been known since the 1950s that the meatal opening in the circumcised penis is significantly smaller than in the intact penis. This finding has recently been confirmed.[Fletcher 2013] The reason the meatus is smaller is most likely because of scarring on the ventral aspect secondary to the loss of blood supply when the frenular artery is interrupted by circumcision. Meatal stenosis has been associated with obstructive uropathy in developing nations. [Eke & Eke 1994] It is unclear why the Task Force tried to ignore the most common complication of circumcision.

Statement 231: "Outside the United States, a cross-sectional study from Nigeria of 370 consecutive male infants (322 of whom had been circumcised) attending an infant welfare clinic for immunization with fair evidence reported an overall complication rate of 20.2%.[186] Complications included redundant prepuce (12.9%), excessive skin removal (5.9%), skin bridge (4.1%), and buried penis (0.4%). The majority of the procedures (81%) were performed in the hospital; 19% were performed at home. Nurses performed 56% of procedures (n = 180), physicians performed 35% (n = 113), and traditional circumcisers performed 9% (n = 29)."

Comment: Irrelevant.

Statement 232: "The Israeli study noted earlier with fair evidence reported a late complication of redundant prepuce in 0.2% of the 19 478 male infants studied.[183]"

Comment: **Misleading**. Methodology would lead to a 10-fold underestimation of the complication rate.

Statement 233: "There is good evidence that circumcision of a premature infant is associated with an increased risk of later-occurring complications (ie, poor cosmesis, increased risk of trapped penis, adhesions). There is also good evidence that circumcision of a newborn who has a prominent suprapubic fat pad or penoscrotal webbing has a higher risk for the same long-term complications.[187]"

Comment: **Unable to confirm**. Published in an obscure journal. However, it does bring up another major complication, ie, buried penis, that the Task Force fails to address. This is a condition that is made worse by circumcision leading to more difficult surgical repairs down the road.[Alter & Ehrlich 1999] The estimate is that this occurs in 1 to 2% of males.[ref 12]

Statement 233: "One prospective study with fair evidence examined the natural course of penile adhesions after circumcision and found that adhesions disappeared at some point 6 months postcircumcision without intervention, except for thick adhesions (called "bridging adhesions"). The authors recommended lysis for skin bridges.[188]"

Comment: Incomplete. Similar data published elsewhere.[ref 76, Van Howe 2001]

Statement 234: "There have been few reports of acute complications after non-newborn circumcision in the United States. Furthermore, there are no adequate studies of late complications in boys undergoing circumcision in the post-newborn period; this area requires more study."

Comment: **Somewhat** inaccurate, contrary to the medical evidence. See comments on meatal stenosis. Several series that have documented meatal stenosis following circumcision are from post-newborn circumcisions.[Stenram et al 1986, Persad et al 1995] The complication of meatal stenosis does not need further study as it has already been studied. However, the full gamut of acute and late complications do require extensive further study in all males circumcised. The fact that they have not been studied is the big reason the AAP cannot state that the benefits outweigh the risks.

Statement 235: "Although adverse outcomes are rare among non-newborn circumcisions, the incidence tends to be orders of magnitude greater for boys circumcised between 1 and 10 years of age, compared with those circumcised as newborns.[189]"

Comment: **Unsubstantiated**. Reference is an abstract. It was based on a national database, which is an inaccurate source of complication data. Such evidence is "poor" because it does not provide

comparative data using the same definition of complications in a population in which data were collected from the two age groups concurrently. The difference noted could be from reporting bias in which one would expect patients who are verbal to call attention to complications while nonverbal infants are less able to call attention to complications. This was noted in one study in which penile findings in boys circumcised as infants were rarely identified as such by parents. [ref 76] Only a handful of studies meet this description. One found no difference in complication rates,[Yegane et al 2006] one found higher rates in newborn circumcision,[ref 229] and two found that the Plastibell had higher complication rates after the newborn period.[Moosa et al 2010, Mousavi & Salehigfar 2008] This statement would be accurate if it limited it to using a Plastibell, and if the correct citations were used. This statement demonstrates again that the literature was not properly reviewed and that articles cited in the report were not carefully analyzed. The Task Force should refrain from using terms such as "rare" without defining the term. This indicates the lack of scholarly rigor that permeates the report.

Statement 236: "As noted, general anesthesia, which is used for procedures performed after the newborn period, confers additional risk."

Comment: **Misleading, unethical, contrary to other AAP policy**. Small trade-off to be afforded *adequate* anesthesia. There is something twisted and sadistic about pushing a procedure at an age when adequate anesthesia is not available, just because the patients are easier to strap down. If a competent adult were to be informed that general anesthesia conferred additional risk above that of local anesthesia, but general anesthesia provided adequate anesthesia and local anesthesia did not, nearly all competent adults would choose general anesthesia.

Statement 237: "[Post-newborn circumcision] The most common surgical complication is excessive bleeding (eg, bleeding that did not stop with local pressure, perhaps requiring a suture), reported in 0.6% of 1742 male infants.[184]"

Comment: **Incomplete, internally inconsistent**. This rate of excessive bleeding is lower than what is reported for infant circumcision, which ranges from 1%[Gee & Ansell 1976] to 9%, [Sutherland, Glueck, & Gleser 1967] suggesting that later circumcision has fewer complications.

Statement 238: "Contact burns were reported with electrocautery when used with metal, and it should not be used with the Gomco clamp in newborn circumcisions because it can cause devastating burns.[184,190,191]"

Comment: Accurate.

Statement 239: "A study with fair evidence reviewed the records of 476 boys undergoing circumcision during childhood and found that complications occurred in 8 records (1.7%), of which 3 were related to anesthesia.[192] The most common surgical complication was excessive bleeding in 0.6%. In another report with fair evidence, which examined 267 patients who had

circumcision by using topical glue rather than skin sutures, excessive bleeding occurred in 0.75% of cases.[193]"

Comment: **Incomplete**, **internally inconsistent**. These complication rates are lower than what is reported for infant circumcision, suggesting that later circumcision has fewer complications. This is inconsistent with the conclusions put forth in this report.

Statement 240: "European centers report an overall complication rate of 1.2% to 3.8% for circumcisions performed in boys during the newborn or non-newborn period.[194–196] In a study with fair evidence of trained medical personnel in the United Kingdom, the rate of bleeding was 0.8% and of infection was 0.3%. In this study of a historical cohort of over 75 boys aged 0 to 14 years, 0.5% required surgical repair.[195]"

Comment: **Incomplete, internally inconsistent**. These complication rates are lower than what is reported for infant circumcision, suggesting that later circumcision has fewer complications.

Statement 241: "In a Turkish prospective cohort study of 700 boys with fair evidence, bleeding was reported in 2.2% of cases and infection in 1.3% of boys circumcised in a hospital, versus a bleeding rate of 3.6% and an infection rate of 2.7% in boys undergoing a nonhospital-based mass religious procedure, despite the latter procedure being performed by trained personnel.[196]"

Comment: **Incomplete, internally consistent**. These complication rates in the hospital are similar to those reported for infant circumcision.

Statement 242: "There are no adequate analytic studies of late complications in boys undergoing circumcision in the post-newborn period."

Comment: **Inaccurate, contrary to the medical evidence, partially accurate**. See comments on meatal stenosis (Statement 230). Several series that have documented meatal stenosis following circumcision are post-newborn circumcisions.[Griffiths et al 1985, Stenram et al 1986b, Stenram et al 1986b, Persad et al 1995] There certainly is a need for thorough studies of all possible late complications (meatal stenosis is just one of these complications), and the studies are not currently adequate. This undermines the statement by the Task Force that "the benefits outweigh the risks" for circumcision when the incidence of the risks is admittedly unknown.

Statement 243: "An Iranian cross-sectional study with good evidence reported a late complication rate of 7.4%, including redundant skin in 3.6%, excessive skin removal in 1.3%, and meatal stenosis in 0.9%.[197]"

Comment: **Schizophrenic**. Didn't the sentence before this say there were no studies and then this sentence gives the findings from a study that supposedly doesn't exist.

Major Complications

Statement 244: "The majority of severe or even catastrophic injuries are so infrequent as to be reported as case reports (and were therefore excluded from this literature review). These rare complications include glans or penile amputation,[198–206] transmission of herpes simplex after mouth-to-penis contact by a mohel (Jewish ritual circumcisers) after circumcision,[207–209] ..."

Comment: Ironic (in a disgusting way), illogical, hyperbolic, incomplete. The chairwoman of the Task Force was in a position to stop the practice of mouth-to-penis contact by mohels, but did nothing. Another report of herpes simplex transmission after mouth-to-penis contact by a mohel came from Israel.[Distel et al 2003] The fact that a catastrophic injury is reported as a case report does not mean that it is "so infrequent." Ignoring the hyperbolic language, while infrequent injuries may be more likely to be reported as case reports, it does not follow that case reports only report infrequent events. Some well-established medical conditions, such as HIV infection, were first reported as case reports. This statement also ignores that many catastrophic injuries are reported as case series. It is certainly pertinent to report ANY injury from an unnecessary cosmetic surgery. Citing nine reports of glans or penile amputation does not give the complete picture of the scope of the problem. The Task Force failed to include a number of case reports and cases series. [Cohen et al 1977, Hashem et al 1999, Sherman et al 1996, Gluckman et al 1995, Hanash 1981, Siegel-Itzkovich 2000, Lerner 1952, Izzidien 1981, Sheffield & Ad-El 2000, Yilmaz et al 1993, Crowley & Kesner 1990, Cetinkaya et al 1993, Magoha 1999, Bozhurt & Ugar 2000, Coskunfirat et al 1999, Audry et al 1994, Aydin et al 2002, Sifen et al 2000, Özkan & Gürpinar 1997, Brimhall 1902, Bierhoff 1912, Ehrich 1929, Gold 1940, Levitt et al 1976, Menahem 1981] A series of seven cases collected over six years published in 1996 in first-line journals was ignored by the Task Force. [Sherman et al 1996] The Task Force appears to be attempting to minimize this serious complication.

Statement 245: "... methicillin-resistant Staphylococcus aureus infection,[210] ..."

Comment: **Inaccurate, not consistent with the medical literature**. Outbreaks of these infections are becoming more commonly reported.[Fortunov et al 2006a, Fortunov et al 2007, James et al 2008, Fortunov et al 2006b, Rothman 2006, Watson et al 2006, Wen & Kowalczyk 2009, Van Howe & Robson 2007] Reference 210 is not a case report or a case series, but a case control study that found circumcised male infants were 12 times more likely to become infected with methicillin-resistant *Staphylococcus aureus* than intact male infants (OR=12.5, 95%CI=1.5-undefined). The difference was statistically significant. Why is the Task Force trying to minimize the importance of this potentionally fatal complication?

Statement 246: "... urethral cutaneous fistula, [211] glans ischemia, [212] and death. [213]"

Comment: **Incomplete, many complications excluded**. One model has suggested that there may be approximately 117 deaths each year in the United States from infant circumcision.[Bollinger 2010] This number is roughly similar to the rate of deaths following male circumcision within

Analysis of 2012 AAP Task Force on Circumcision Report

the medical system in Brazil.[Korkes et al 2012] By listing one citation for each of these serious complications the Task Force is giving the impression that these complications have only been reported once in the medical literature. Urethral cutaneous fistula and other urethral injuries have been reported multiple times.[ref 198, Lau & Ong 1981, Bierhoff 1912, Lackey et al 1969, Baskin et al 1997, Chapel 2000, Johnson 1949, Colodny et al 1994, Limaye & Hancock 1968, 1968, Shiraki 1973, Guralnick et al 2000, Aköz et al 1998, Kiliç et al 2000, Byars & Trier 1958, Benchekroun et al 1981] The same is true for glans ischemia.[ref 206, Smith et al 1994, Özdemir 1997, Stefan 1992, Stefan 1994, Sterenberg et al 1981, Crowley & Kesner 1990, Woodside 1980, Rosefsky 1967, Brown & Fryer 1958, Diamond & Sigmundson 1997] The Task Force is disingenuous in only citing a report of deaths following ritual circumcision in Africa. Each year there are reports of multiple deaths following ritual circumcision. Deaths following circumcision in hospital and clinic settings have been reported repeatedly in the medical literature.[Meel et al 2010] The Task Force needs to acknowledge there are deaths following circumcisions performed in medical settings.[Pediatric Death Review Committee 2007, McMilan 2007, Gairdner 1949, Burger & Guthrie 1974, Clearly & Kahn 1979, Sullivan 2002, Birrell 1965]

There are a number of serious complications that have been repeatedly documented in the medical literature that the Task Force failed to mention. These include burns from electrocautery, [Aköz et al 1998, Stefan 1992, Stefan 1994, Belkacem et al 1997, Wilson & Wilson 1959, Diamond & Sigmundson 1997, Bradley et al 1998, Sharpe & Finney 1982, Pearlstein 1981, Belman 1981, Perlman 1976, Money 1998] staphylococcal scalded skin, [Annunziato & Goldblum 1978, Andy & Kobori 1982, Curran & Al-Salihi 1980, Stranko et al 1986] tetanus (primarily in developing countries, Schulman 1895, Gosden 1935, D A Nishroka 2000, Sow et al 1993, Bennett et al 1996, Bennett et al 1999, Mallory 1995] septicemia, [Birrell 1965, Fredman 1969, Dunham 1933, Crowley & Kesner 1990, Stringer 1991, Manji 2000, Magoha et al 1999, Kirkpatrick & Eitzman 1974] osteomyelitis, [Birrell 1970, Altman 1946, Stringer 1991, Sze 1982] Fornier's gangrene, [Woodside 1980, Menahem 1981, Susan et al 1978, Adeyokunnu 1983, Evbuomwan & Aliu 1984, Adams et al 1990, Sawin et al 1981, Kurul 1995, Woodside et al 1981, de Toit & Villet 1979, Hamm & Kanthak 1949, Wilson & Wilson 1959, Thorek & Egel 1949, Ahmed et al 1994, Bliss et al 1997] too much skin removed (including degloving and total denudation), [ref 202, Wilson & Wilson 1959, Oreozco-Sanchez & Neri-Vela 1991, Smey 1985, Sotolongo et al 1985, Brown 1937, Fisher 1954, Bettencourt & Costabile 1996, Ezell et al 1969, Madden & Boddy 1991, Greenberg 1999, Van Duyn & Warr 1962, Schechet & Fried 1997, Baker & Gonzalez 1961, Crowley & Kesner 1990] acute urinary retention, [ref 205, Shulman et al 2000, Pearce 2000, Gee & Ansell 1976, Horowitz et al 1976, Ly & Sankara 2003, Jee & Millar 1990, Craig et al 1994, Eason et al 1994, Griffith et al 1985] retention of Plastibell ring (including pseudoparaphimosis) which can follow 11% of procedures, [Lawton 1965, Datta & Zinner 1977, Rubinstein & Bason 1968, Owen & Kitson 1990, Johnsonbaugh et al 1969, Johnsonbaugh et al 1979, Client et al 1999, Madden & Boddy 1991, Mihssin et al 1999, Gee & Ansell 1976, Moreno & Realign 1989, Shah et al 1999, Reppin & Romer 1985, Wright 1967], and hair strangulation (penile tourniquet syndrome) in which 69 of 70 reported cases are in circumcised boys.[Pantuck et al 1997, Sheinfeld et al 1985, Bashir & El Barbary 1980, Aboulola

et al 1980, Haddad 1982, Haddad 1985, Livne & Gonzales 1985, Mhiri et al 1987, El-Bahnasawy & El-Sherbiny 2002, Toguri et al 1979]

Statement 247: "In general, untrained providers create more complications when performing male circumcision than do well-trained providers, regardless of whether they are physicians, nurses, or traditional religious providers. Physicians in a hospital setting generally have fewer complications than traditional providers in the community setting."

Comment: **Unsubstantiated, not supported by the medical literature**. No citation given. Any data in North America? Only one study has looked at complication rates on the basis of amount of medical training. In a Family Practice residency program in Texas, first-year residents had a complication rate of 5.6%, second-year residents 6.8%, and third-year residents 7.1%. The difference was not statistically significant (p=.9664 overall, p=.8132 for trend), but certainly the trend was in the wrong direction.[Moreno & Realign 1989] In many hospitals, it is the residents in training who perform the majority of circumcisions, but this finding may suggest that the more senior resident may be more careless in performing the procedure.

Statement 248: "A prospective study in Kenya with good evidence found an overall complication rate of 35% in 443 children and young men aged 5 to 21 years who had traditional circumcision performed in a village or household setting, compared with an overall complication rate of 17% in those whose circumcision was performed by trained providers in a medical setting such as a hospital, health center, or physician's office.[214] The most common complications were bleeding and infection; excessive pain, lacerations, torsion, and erectile dysfunction were also observed. A study in Turkey with fair evidence studied a historical cohort and found a significantly higher rate of complications when male circumcision was performed by traditional circumcisers, compared with those performed by physicians; complication rates were 85% for traditional providers versus 2.6% for physicians.[215]"

Comment: Irrelevant.

Statement 249: "A study in Israel with fair evidence found there was no difference in the rate of complications in newborn circumcision between hospital-based physicians and well-trained, home-based ritual circumcisers (mohels).[183]"

Comment: **Dubious**. The data collection method in Reference 183 would markedly underestimate the number of complications identified, so this finding is suspect.

Statement 250: "There have been few studies comparing the 3 most commonly used techniques for male circumcision in the United States (the Gomco clamp, the Plastibell device, and the Mogen clamp). Steps common to all 3 include estimation of the amount of external skin to be removed; dilation of the preputial orifice so the glans can be visualized to ensure that the glans itself is normal; bluntly freeing the inner preputial epithelium from the epithelium of the glans;

placing the device; leaving the device in place long enough to produce hemostasis; and surgically removing the foreskin."

Comment: Irrelevant.

Statement 251: "The Gomco clamp was specifically designed for performing circumcisions. In this procedure, "the foreskin is cut lengthwise through the stretched tissue (dorsal slit) to allow space to insert the circumcision device. The bell of the Gomco clamp is placed over the glans, and the foreskin is pulled over the bell. The base of the Gomco clamp is placed over the bell, and the Gomco clamp's arm is fitted. After the surgeon confirms correct fitting and placement (and the amount of foreskin to be excised), the nut on the Gomco clamp is tightened and left in place for 3 to 5 minutes to allow hemostasis to occur, then the foreskin is removed using a scalpel. The Gomco's base and bell are then removed.[216]"

Comment: Accurate.

Statement 252: "One study of the Gomco clamp with fair evidence reviewed 1000 newborn circumcisions in a hospital setting in Saudi Arabia and found an overall complication rate of 1.9%.[185] Bleeding occurred in 0.6% of cases, infection in 0.4%, and redundant prepuce in 0.3%. Another study of 521 newborn male circumcisions performed at a Houston outpatient clinic with fair evidence reported a 2.9% incidence of phimosis (trapped penis) after newborn circumcision using the Gomco clamp.[217]"

Comment: Accurate.

Statement 253: "Plastibell circumcision involves a surgical procedure in which a plastic ring is inserted under the foreskin, and a tie is placed over the ring to provide hemostasis. The ring remains on the penis for several days until the tissue necroses and the ring falls off spontaneously. Bleeding ranged from 0.8% to 3% of cases; infection occurred in 2.1% of cases. [218] Urinary retention[219,220] and problems with the Plastibell ring have been reported in 3.6% of cases.[221] Studies of the Plastibell device with fair and good evidence found, overall, that complications range from 2.4% to 5%.[218,221–223]"

Comment: **Incomplete**. The Plastibell ring can fail to fall off the penis within a week in 3.57% [Shah et al 1999] to 11%.[Wright 1967] Pseudoparaphimosis occurs when a plastic ring left behind following use of a plastic bell circumcision device impedes venous blood flow. Instead of falling off with the crushed necrotic tissue distal to the ligature, the plastic ring works its way proximally along the shaft of the penis until it becomes wedged in place. Swelling results, which makes the plastic ring more firmly entrenched. This has been reported to occur following Plastibell circumcisions in 0.27%[Gee & Ansell 1976] to 1%[Rubenstein & Bason 1968] to 1.6%.[Moreno & Realini 1989] This can lead to serious complications.[Bode, Ikhisemojie, & Ademujiwa 2010] Horrific infections also seem to be more common with the Plastibell. [ref 220]

Statement 254: "The Mogen clamp is a device consisting of 2 flat blades that have a limited (slitlike) space between them and a mechanism that draws the blades together and locks them in place. The slit is limited to 3 mm to allow the foreskin, but not the glans, to cross the opening. The preputial adhesions are gently taken down by a probe and the glans pushed downward, thereby protecting it from the blades. The prepuce distal to the glans is drawn into the slit between the blades and positioned. The blades are locked together, crushing the skin and creating hemostasis. The skin is excised from above the clamp. The clamp is removed and the skin pushed proximally into proper position."

Comment: Accurate.

Statement 255: "There were no specific studies of complications of the Mogen because complications are rare; thus, one can only rely on available case reports of amputation. [201,202,222–228]"

Comment: **Unsubstantiated, incomplete**. How can it be stated that complications are rare when there are no specific studies? The company that distributes Mogen clamps has been shut down following more than \$10 million in product liability judgments, primarily from cases in which the glans was partially amputated.[D.P., Jr. v. Kendall and Sonyika 2006] Amputation of the glans penis is indeed a serious complication that warrants discussion whether documented through "specific studies" or through case reports or case series.[Sherman et al] Often, the most notable complications are only found in case reports. This is how the FDA and vaccine registry keep track of problems related to medications or vaccines, by individual reporting of patient cases. Someone must have been collecting data on problems arising from the Mogen clamp, otherwise there would not have been the need for publications in *Health Devices* warning of problems associated with use of this type of clamp.[ref 200, Health Devices 1997, Health Devices 2000]

Statement 256: "A study with fair evidence evaluated the use of the Gomco versus the Plastibell device in 350 newborn infants.[229] The incidence of infection was higher with the Gomco clamp (2%) versus a lower complication rate (1.3%) with the Plastibell device. Adhesions were also more common with the Gomco clamp, at a rate of 20% vs 6.6% for the Plastibell device."

Comment: Accurate, incomplete. In an older study, infections were significantly more common in circumcisions performed with the Plastibell than those performed with a Gomco (0.72% versus 0.14%, OR=5.27, 95%CI=1.75-21.32).[Gee & Ansell 1976] The report fails to note that in Reference 229, the incidence of complications was higher following newborn circumcision than circumcisions performed after the newborn period.

Statement 257: "Based on the data reviewed, it is difficult, if not impossible, to adequately assess the total impact of complications, because the data are scant and inconsistent regarding the severity of complications."

Comment: **Incomplete, illogical**. If it is "difficult, if not impossible, to adequately assess the total impact of complications", then how can the Task Force come to the conclusion that the benefits outweigh the risks? In order to make this calculation, they need estimates of the impact of the benefits and the risks, but the Task Force does not provide estimates of the impact of either.

<u>Update</u>: In response to subsequent criticism, the Task Force stated that it felt the benefits outweighed the risks.[AAP Task Force 2013]

Statement 258: "For example, studies that report bleeding as a complication do not uniformly report how frequently the bleeding was controlled with local measures versus requiring a transfusion or surgical intervention. Similarly, infection is rarely further divided into local tissue infection versus bacteremia or sepsis. Financial costs of care, emotional tolls, or the need for future corrective surgery (with the attendant anesthetic risks, family stress, and expense) are unknown."

Comment: Accurate.

Statement 259: "Some reports have attempted to compare potential benefits of circumcision with reported complication rates. One study with good evidence attempted to estimate complication rates compared with benefits from male circumcision. Based on an estimate that 100 circumcisions must be performed to prevent 1 UTI, and 909 circumcisions must be performed to prevent 1 case of penile cancer, the study yields an estimate of 1 complication for every 5 UTIs prevented and 2 complications for every 1 case of penile cancer prevented.[121]"

Comment: **Inaccurate, incomplete**. Reference 121, because of its design, would underestimate the incidence of immediate complications by a factor of 10 or more (See Statement 172). A full cost-utility analysis comparing the potential benefits and reported complication rates was published in 2004. Based on best estimates, it found that over a lifetime, neonatal circumcision increased incremental costs by \$828. 42 per patient and resulted in an incremental 15.30 well-years lost per 1000 persons. It also found that if neonatal circumcision was cost-free, pain-free, and had no immediate complications, it was still more costly than not circumcising. Using sensitivity analysis, it was impossible to arrange a scenario, including one in which every variable maximally favored circumcision, that made neonatal circumcision cost-effective.[Van Howe 2004] The information used to form the basis of the analysis has not appreciably changed since the study was published, so there is little reason to believe that the findings of this analysis are invalid. It is odd that this study was not included by the Task Force unless the Task Force deliberately avoided the inclusion of this damaging analysis.

Statement 260: "Assuming an overall minor adverse event rate for newborn circumcision of 0.2%, and a severe adverse event rate of 0.005%, another study with fair evidence estimated that over 322 000 newborn male circumcisions are required to prevent 1 case of penile cancer per year.[122] Similar modeling for HIV, herpes, and HPV in the United States is not available."

Analysis of 2012 AAP Task Force on Circumcision Report

Comment: **Inaccurate, statements not supported by the citation**. Modeling of these infections were included in a cost-utility analysis.[Van Howe 2004] This assumption is far outside the realm of reality. Minor complications have been repeatedly documented to occur at more than ten times this frequency. As discussed in Statements 173 and 174, the one in 322,000 figure is inaccurate and reflects yearly risk as opposed to lifetime risk. Furthermore, Reference 122 did not include any modeling of data.

Statement 261: "A recently published CDC study found that male circumcision before the age of sexual debut was cost-effective for the prevention of HIV.[60]"

Comment: **Inaccurate**. The serious, fatal flaws of Reference 60 have been discussed earlier (Statement 97). It is also inappropriate to call a modeling exercise a "study" as no direct data are collected.

Statement 262: "The study did not take into account the positive benefits of newborn circumcision for other conditions such as costs of caring for UTIs.[106,107,110,112,230–233]"

Comment: **Incomplete, overkill, inappropriate citation**. These factors were considered in a cost-utility analysis, which failed to show any positive benefits to newborn circumcision.[Van Howe 2004] The "study" also did not take into account that circumcision had *any* complications. It is not clear why the Task Force cited 8 studies that relate to circumcision and urinary tract infections when Reference 106 was a systematic review that included References 107, 110, 112, 230, 231,232, and 233. Given the paucity of citations in the report and the hundreds of citations that were not included, why pad the reference list with redundant citations (especially citations 230, 231, 232, 233 that were not used elsewhere in the report) unless the Task Force felt the need to bolster their pro-circumcision position. Reference 233 is a review article, which has no place in this report.

Statement 263: "It also did not include recent evidence that circumcision (either as an infant or later in life) is associated with reduced risk for other STIs, penile and cervical cancers, phimosis, and penile dermatoses.[36,88,234,235] The authors did not include adverse effects that make newborn circumcision less cost-effective, such as bleeding, infection, and revision."

Comment: **Incomplete**. These factors were considered in a cost-utility analysis, which did not show a reduced risk for STIs, penile and cervical cancers, phimosis and penile dermatoses.[Van Howe 2004] It appears that the Task Force used this as an opportunity to iterate its talking points. Each of these is discussed individually elsewhere in this document.

Statement 264: "Considering all these factors, however, the authors concluded that male circumcision was a cost-effective strategy for HIV prevention in the United States.[60]"

Comment: **Inaccurate, hyperbole**. The serious, fatal flaws of Reference 60 have been discussed earlier (Statement 97). Statements 262, 263, and 264 reflect nearly verbatim the hyperbolic propaganda of circumcision enthusiasts such as Schoen and Morris,[Schoen et al 2006, Morris et al 2006] and reveals the underlying pro-circumcision bias of the Task Force.

Recommendation C (restated): "Physicians counseling families about elective male circumcision should assist parents by explaining, in a nonbiased manner, the potential benefits and risks, and by ensuring that they understand the elective nature of the procedure."

Comment: **Unethical, inconsistent with other AAP policy**. There is a legitimate debate over whether parents have the authority to give proxy consent for the procedure.[ref 9, Svoboda, Van Howe, & Dwyer 2000] The average physician cannot provide this information since the Task Force (and the CDC) has failed to provide accurate information that is nonbiased. It has also been documented that the information provided may be biased based on whether the provider is circumcised or has children that are circumcised.[Muller 2010]

Recommendation D (restated): "Parents are entitled to factually correct, nonbiased information about circumcision that should be provided before conception and early in pregnancy, when parents are most likely to be weighing the option of circumcision of a male child."

Comment: **Unethical, inconsistent with other AAP policy**. There is a legitimate debate over whether parents have the authority to give proxy consent for the procedure.[ref 9, Svoboda, Van Howe, & Dwyer 2000] The Task Force has failed to provide factually correct, nonbiased information. Parents are entitled to information about the normal penis including the structure, function, and development of the foreskin, as well as correct information on how to care for normal genitals. Providing the biased information the Task Force has put forth in their recommendations, before conception or early in pregnancy would be little more than unethical solicitation of unnecessary surgery.

Recommendation E (restated): "Parents of newborn boys should be instructed in the care of the penis at the time of discharge from the newborn hospital stay, regardless of whether the newborn is circumcised or not."

Comment: Accurate, **Incomplete**. Parents should be told during the disclosure portion of the informed consent process, that while the circumcised penis requires specific care, the intact penis does not require any specific care and is best left alone.

Recommendation F&G (restated): "Male circumcision should be performed by trained and competent practitioners, by using sterile techniques and effective pain management. Analgesiais safe and effective in reducing the procedural pain associated with newborn circumcision; thus, adequate analgesia should be provided whenever newborn circumcision is performed."

Comment: **Inaccurate**. Adequate anesthesia in not safely available for neonatal circumcision. The anesthesia currently available is not completely effective.

Recommendation J (restated): "Key professional organizations (AAP, AAFP, ACOG, the American Society of Anesthesiologists, the American College of Nurse Midwives, and other midlevel clinicians such as nurse practitioners) should work collaboratively to:

Develop standards of trainee proficiency in performance of anesthetic and procedure techniques, including suturing;"

Comment: Redundant.

Recommendation K (restated): "Teach the procedure and analgesic techniques during postgraduate training programs;"

Comment: **Unethical, inconsistent with other AAP policy**. Why should we teach analgesic techniques that we know do not provide adequate anesthesia? This only results in a procedure that is both unnecessary and painful. The report fails to acknowledge that some trainees may find the practice of infant male circumcision a contradiction to their personal ethical beliefs, and the report fails to provide for the option of conscientious objection.[Storms 2013]

Recommendation M (restated): "Offer educational materials to assist parents of male infants with the care of both circumcised and uncircumcised penises."

Comment: Accurate, inflammatory language. Referring to "uncircumcised penises" is like referring to unmastectomized breasts or unclitoridectomized vulva. "Uncircumcised" is a pejorative term. [Wallace 2015]

Statement 265: "There is fair evidence that some clinicians do not convey current or medically accurate information about circumcision to parents, either verbally or in written materials.[18] Providing information about the risks and benefits of circumcision does not seem to lead to lower circumcision rates.[236]"

Comment: **Incomplete**. In one study, circumcised male physicians were almost five times more likely to recommend circumcision. Physicians whose own sons were circumcised were six times more likely to recommend circumcision.[Muller 2010] This study goes a long way towards explaining the thought processes and biases of the current Task Force.

Statement 266: "As noted, in 2009, the AAP surveyed members on their attitudes and practices around circumcision.[19] According to the responses, 67% of pediatricians reported discussing the pros and cons of circumcision with parents. Almost two-thirds (62%) reported that they made no recommendation regarding circumcision to the majority of their patients; 18% responded recommending to all or most of their patients' parents that circumcision be performed; 7%

reported recommending to all or nearly all of the parents of newborn males that circumcision not be performed."

Comment: **Ironic**. This indicates that by pushing circumcision, the Task Force is in a small minority of AAP members and their opinion does not match that of the AAP membership; however, merely bringing up the topic indicates a bias in favor of circumcision on the part of the pediatrician.

Statement 267: "As described earlier, there is fair evidence that parental decision-making about circumcision tends to occur well before the child's birth. Thus, information to assist in parental decision-making should be made available as early as possible, even as part of guidance to parents before conception occurs."

Comment: **Unethical, inconsistent with other AAP policy**. There is a legitimate debate over whether parents have the authority to give proxy consent for the procedure.[ref 9, Svoboda, Van Howe, & Dwyer 2000] There is also the problem of solicitation as discussed earlier (Recommendation B).

Statement 268: "For this reason, obstetrician-gynecologists and family physicians who manage women's health and prenatal care probably have a more pivotal role in this decision than do pediatricians. Public health authorities have an important role in educating the public on the role of newborn male circumcision in disease prevention."

Comment: **Unethical, inconsistent with other AAP policy**. There is a legitimate debate over whether parents have the authority to give proxy consent for the procedure.[ref 9, Svoboda, Van Howe, & Dwyer 2000] There also needs to be discussion of the dubious ethics surrounding newborn circumcision. This statement indicates another push by the Task Force to get as many healthcare professionals as possible involved in promoting circumcision.

Statement 269: "In the United States, obstetricians, family physicians, and pediatricians are the principal clinicians who perform newborn circumcisions in medical settings; there is no single system of training or credentialing for circumcision in use nationwide.[237] There is good and fair evidence of considerable variation in provider type by region and by hospital,[238–240] with midwives performing circumcision in some locations.[18,241]"

Comment: Accurate, unethical. Violation of infants human rights and Hippocratic Oath.

Statement 270: "Training curricula for teaching newborn circumcision in departments of pediatrics[237,242] and family medicine[243] have been described but do not provide information on how widely used they are or the trainings' results and/ or effectiveness."

Comment: **Unethical, incomplete**. Violation of infants human rights and Hippocratic Oath. Also, residents need to be able to be conscientious objectors without fear of reprisal.[Storms 2013]

Statement 271: "One pediatric program's training consisted of the resident performing 3 to 5 circumcisions with assistance from a faculty instructor, 3 to 5 circumcisions under direct observation but without hands-on faculty involvement, and 2 test circumcisions for grading and departmental credentialing.[242] The other 2 programs did not describe actual resident experience performing a circumcision. Most residency training programs in the respective specialties teach techniques, including the Gomco clamp, Mogen clamp, and Plastibell device. [238] As of 2006, 97% of programs that included training in performance of circumcision taught the use of either local or topical anesthetics for circumcision analgesia, an increase from 45% to 74% in 1998.[238–240] Although case studies were excluded from this review, it was noted that 2 record reviews with fair evidence addressed the need for circumcision revision based on the medical discipline of the physician who performed the original procedure.[241,244]"

Comment: **Unethical, internal inconsistency, inconsequential, not supported by citation**. Violation of infants human rights and Hippocratic Oath. Also, residents need to be able to be conscientious objectors without fear of reprisal.[Storms 2013] The Task Force excluded case studies from review because they were considered to be of poor quality, yet when two record reviews are included here, they are considered to provide "fair" evidence. The specialty of the physician who performed the initial circumcision in cases in which a circumcision revision was performed does not provide any useful information unless it is known the distribution of physician type performing newborn circumcisions within the referral catch basin. Reference 244 did not differentiate by the medical discipline of the physician who performed the original procedure but by whether the procedure had been performed by a medical professional or a layman.

Statement 272: "None of the articles reviewed addressed current or future workforce needs, which seems to depend on the number of surgeries being performed, the future demand, and reimbursement for the procedure. Sustaining a workforce that is capable of counseling families and performing the newborn male circumcision procedure safely is increasingly important, as the number of clinicians who are able to perform this procedure is likely to decline with curtailment of Medicaid coverage for it in various states."

Comment: **True motive, fabrication, incomplete, illogical**. Is it really all about increasing the demand, to keep the money rolling in? There is not a lack of physicians who perform circumcisions. Currently, within the United States, any parent who wants their son circumcised, and has the money or the insurance to pay for the procedure, should have no difficulty finding a medical professional willing to do so. There are no plans on the national level to decrease the number of training positions in pediatrics, obstetrics, or family medicine. There is no evidence of any plans to stop offering circumcision training to these residents. Curtailment of Medicaid coverage in various states should not have any impact on the number of providers who perform circumcisions. It is illogical non sequitur to think that these two issues would be connected.

What will more likely affect supply first is the number of physicians in training who conscientiously object to performing circumcisions on non-consenting newborns. This will take place because the generation of males currently in medical school is less likely to be circumcised than the generation before. They are less likely to accept the contents of this report and more likely to identify newborn circumcision as a human rights violation. Likewise, the females currently in medical school are more familiar with intact males than their counterparts a generation earlier and will not be swayed by the contents of this report. This may decrease supply before there is a drop in demand.

The drop in demand is ongoing, and is likely to continue, given that the popularity of infant circumcision is falling and efforts to limit newborn circumcision (primarily through limited insurance coverage and peer pressure) continue to escalate. At a certain tipping point in circumcision incidence, demand will drop off sharply. It is not known where that tipping point is. In other countries where circumcision once was popular, but is now rarely performed, it was physician refusal to perform circumcision that led to a decrease in demand for the procedure. That will likely be a late step in the process in the United States. As one European physician attending the AAP national convention said, "You won't stop doctors in America from circumcising babies because they want the money." In other countries, national health insurance stopped covering the procedure and the demand decreased dramatically.

The Task Force's failure to comprehend this simple interaction of supply and demand also helps explain the bias of this report. Rather than realizing that demand for circumcision is decreasing, that third-party payers are tightening their belts and are unwilling to pay for cosmetic procedures, that pediatricians/physicians are less likely to circumcise their children compared to the general population, and that calls to respect the rights of children are increasing in volume, the Task Force adopted a reactionary bunker strategy. This Task Force report and the 2014 draft recommendation from the Centers for Disease Control and Prevention now stand alone as the only documents published by national medical organizations that portray newborn circumcision in a favorable light. Was the Task Force realistically thinking they could hold back the tide? By taking their position, the AAP is now going to miss the boat.

A better, more rational approach would be to accept the change in sentiment that is building, and adopt an exit strategy. The Task Force missed a great opportunity, instead they embarrassed a great organization dedicated to providing the best health care for children.

Recommendation O: "A structured decision-making tool that clinicians can use to help parents complete would assist in the decision of whether to circumcise or not."

Comment: **True motive, unethical**. It's all about increasing the demand, to keep the money rolling in. There is a legitimate debate over whether parents have the authority to give proxy consent for the procedure.[ref 9, Svoboda, Van Howe, & Dwyer 2000]

Statement 273: "To this end, the Task Force recommends that key professional organizations (AAP, ACOG, AAFP, American Society of Anesthesiologists, American College of Nurse Midwives, and other entities supporting midlevel clinicians) work together to develop a consensus plan about which groups are best suited to perform circumcisions in newborn males; teach the procedure and analgesic techniques during postgraduate training programs; and develop standards of trainee proficiency. In addition, health departments should be involved in the dissemination of educational materials and coordinating educational efforts with professional organizations."

Comment: **True motive, out of step**. It's all about increasing the demand, to keep the money rolling in. The Task Force has ignored all of the evidence and signals that circumcision is dying a slow death.

Statement 274: "The CDC estimates that, from 2005 to 2006, the average cost of providing newborn male circumcision (including physician- and facility-related costs) ranged from \$216 to \$601 across the nation.[60] Hospitals in states where Medicaid covers routine newborn male circumcision have circumcision rates that are 24% higher than hospitals in states without such coverage.[23] As of 2009, 15 states did not cover newborn male circumcision in their Medicaid programs; 2 additional states had variable coverage dependent on the enrollment plan.[245] There seems to be a relationship between circumcision incidence and third-party payment."

Comment: **True motive, inaccurate**. It's all about increasing the demand, to keep the money rolling in. There is a difference between charges and costs. The dollar figures sound like charges. For example, a physician can charge Medicaid whatever they please, but will only be reimbursed so much. There are now 18 states that do not cover infant circumcision in their Medicaid program because they do not think it is cost effective. Looking at national Medicaid policy, none of the states should be funding this procedure because it is non-therapeutic.[Adler 2011] If the mission of the AAP is the health and well-being of children, why this outrageous focus on the money? The Task Force was not given a specific charge. They reviewed the topics that were of interest to them. The choice to include reimbursement issues is a poor reflection on the professionalism and motivations of the Task Force membership. This discussion comes across as crass, avaricious, and self-serving. It appears to be an attempt to protect physicians from liability for performing an unnecessary, cosmetic surgery done on human beings who cannot consent to the removal of their healthy genital tissue. This impression is amplified by the number of times the report begs third-party payers to keep the money coming.

Statement 275: "Circumcised newborns are more likely to be privately insured than publicly insured infants.[246] The weighted rates of circumcision over the 13-year period from 1991 to 2005 were 40.8% for Medicaid clients versus 43.3% for the uninsured and 64.4% for insured newborns.[5] The associations with insurance status were independent of race/ethnicity and socioeconomic status in this study.[246]"

Comment: **True motive**. It's all about increasing demand, to keep the money rolling in. Interestingly, when controlled for type of insurance (private versus public) Blacks have significantly higher infant circumcision rates than Caucasians.

Statement 276: "As noted, a recent cost-effectiveness analysis by the CDC concluded that newborn circumcision is a societal cost-saving HIV prevention intervention.[60]"

Comment: **Inaccurate**. The weaknesses of Reference 60 are discussed in Statement 97. A more complete cost-utility analysis was published in 2004[Van Howe] and ignored by the Task Force. Another example of selection bias on the part of the Task Force. Again, the same attempt to convince physicians and the public how wonderful circumcision is for the country.

Statement 277: "African-American and Hispanic males in the United States are disproportionately affected by HIV and other STIs, and thus would derive the greatest benefit from circumcision; the HIV prevention evidence for non-Hispanic white males was not as strong as for African-American and Hispanic males."

Comment: **Inaccurate, inconsistent with medical evidence, racist**. Heterosexual African-American males have much higher rates of HIV infection compared to heterosexual Hispanic males, yet the circumcision rate is already two to three times higher in African-Americans. There is some cognitive dissonance that must be overcome to recommend circumcision to the ethnic group with the highest prevalence of both HIV infection and circumcision.. Either circumcision has little or no impact on HIV risk (most likely) or there are other factors that are much more important in the transmission of HIV (intravenous drug use, sexual mixing patterns, etc.). It is likely both. In either case, our resources should be directed at reducing the impact of those other factors, or towards secondary prevention measures such as "treatment-as-prevention" or preexposure prophylaxis of HIV. Some have recommended infant circumcision specifically for these minority populations.[Gray et al 2009] To be consistent with this information, the Task Force should have said that infant circumcision is not needed for Caucasians because it is not costeffective for them,[ref 60] but that would be racist.

Statement 278: "However, the African-American and Hispanic populations are the most likely to have Medicaid coverage.[247] In 2010, 50% of Hispanic children (up to age 18 years) and 54% of African-American children were covered by Medicaid, compared with 23% of white children. [248] Thus, recent efforts by state Medicaid programs to curb payment for newborn male circumcision affect those populations that could benefit the most from the procedure.[60] The CDC authors recommended that: "Financial barriers that prevent parents from having the choice to circumcise their male newborns should be reduced or eliminated.""

Comment: **True motive, inconsistent with reality, racial overtones**. It's all about increasing the demand, to keep the money rolling in. There is no citation other than the bogus study. How is it that Hispanic males who live in the United States have a higher prevalence of HIV infection than Hispanic males who live in Mexico? The circumcision prevalence of Hispanic males in the

United States is also higher than in Mexico. Circumcision obviously has failed to decrease HIV infections. Singling out African-American and Hispanic males also has racial overtones: the unspoken message is that these groups do not have the capacity (physically, mentally, or financially) to avoid HIV infection, so, in a move of pure paternalism, we must implement circumcision. (How much HIV infection in minorities can be attributed to IV drug usage with a lack of sterile needles, which would be unaffected by circumcision?) Similar racist attitudes are seen in the effort to circumcise males in Africa. If the results of Reference 60 are to be believed (and there are many reasons to not believe them), then it is not cost-effective to circumcise Caucasian males, but cost-effective to circumcise African-American and Hispanic males. If the recommendations of the Task Force are data driven (which they are not), then it should be stated that white males can be exempted from circumcision. This would be consistent with the position taken by the researchers at Johns Hopkins.[Gray et al 2009] Since the above statement is nearly identical to his opinion piece, why didn't the Task Force list it as a citation? Another example where the Task Force's opinions are directly drawn from the opinions of known circumcision enthusiasts.

AREAS FOR FUTURE RESEARCH

Statement 279: "In the course of its work, the Task Force identified important gaps in our knowledge of male circumcision and urges the research community to seriously consider these gaps as future research agendas are developed. Although it is clear that there is good evidence on the risks and benefits of male circumcision, it will be useful for this benefit to be more precisely defined in a US setting and to monitor adverse events. Specifically, the Task Force recommends additional studies to better understand:"

Comment: **Self-contradiction**. Earlier in the report it was stated that there was a lack of good evidence on risks. Wouldn't it be even more useful for the risks to "be more precisely defined in a US setting?" The risks are of primary importance because this is a cosmetic surgery that removes normal healthy tissue. This surgery does not diagnose or treat any disease process.

Statement 280: "The performance of elective male circumcisions in the United States, including those that are hospital-based and nonhospital-based, in infancy and subsequently in life."

Comment: **Inconsequential**. Why does this matter? If it is just a snip under local anesthetic, why would the setting matter? If there is a difference, so what? who cares? The only reason to pursue this is to use the data to drive more of the procedures into a medical setting to improve market share. It is a way for physicians to determine where to place additional pressure for conformity, marketing, and outreach purposes.

Statement 281: "Parental decision-making to develop useful tools for communication between providers and parents on the issue of male circumcision."

Comment: **Propaganda, unethical**. This is just to shore up the demand side of circumcision to keep the money flowing in from circumcisions, and to keep circumcision the "norm" in the US. How about developing tools that are not biased and discuss the human rights and legal issues? Are parents aware that their children could sue them later for having them circumcised without their consent? There is legitimate debate over whether parents have the authority to give proxy consent for the procedure.[ref 9, Svoboda, Van Howe, & Dwyer 2000, Van Howe (JME) 2013] Where is the discussion about "communication between providers and parents" on the normality of intactness, wholeness, completeness of one's genitals?

Statement 282: "The impact of male circumcision on transmission of HIV and other STIs in the United States because key studies to date have been performed in African populations with HIV burdens that are epidemiologically different from HIV in the United States."

Comment: **Unnecessary**. The information is already available in North America (Statement 97), the Task Force merely doesn't like the negative results and is calling for more studies until one yields the results they want. This statement also reveals that they are promoting a procedure in the US that is unlikely to be of any benefit. Finally they concede that the African RCT's have no basis for the development of medical policy in the US.

Statement 283: "The risk of acquisition of HIV and other STIs in 0- to 18-year-olds, to help inform the acceptance of the procedure during infancy versus deferring the decision to perform circumcision (and thus the procedure's benefits) until the child can provide his own assent/ consent. Because newborn male circumcision is less expensive and more widely available, a delay often means that circumcision does not occur. It will be useful to more precisely define the prevention benefits conferred by male circumcision to inform parental decision-making and to evaluate cost-effectiveness and benefits of circumcision, especially in terms of numbers needed to treat to prevent specific outcomes."

Comment: **Propaganda, false ignorance, inconsistent with other AAP policy**. The AAP is afraid that older male children, male adolescents, and adult males will not agree to circumcision, which of course is precisely why infants are now being forced to undergo circumcisions. There is no objective evidence to show that infant circumcision decreases or prevents STIs or HIV. Infants and children are not sexually active and not at risk for any STIs or sexually transmitted HIV. North American studies do not support any benefits to circumcision, but do show the opposite. Intact males are at lower risk of STIs including HIV.[Van Howe STIs 2013]

The above statement by the AAP is just to shore up the demand side of circumcision to keep the money flowing in from circumcisions. There is a window between when a child can begin giving fully informed consent and when sexual activity begins.[ref 9] This position appears to assume that an adolescent cannot learn to use condoms or other safe-sex practices. The data the AAP relies on is derived from studies of adult men. There are no studies of infant circumcision that have found the same conclusions. It is reasonable to wait until the age of consent because the patient has options to choose from, several of which are more effective, less costly, and less

invasive than circumcision. It is a more reasonable choice for someone to rely on condoms to protect against STIs and keep their penis intact than to have a circumcision and not use condoms.

The Task Force fails to address the issue of risk compensation.[Blower & McLean 1994] If a circumcised male believes that his circumcision protects him from STIs and HIV infection, he will be less likely to use a condom and thus will increase his risk of becoming infected. This is already happening in Uganda. Uganda was able to cut the incidence of HIV infection in half by using the ABC (Abstinence, Be faithful, Condoms) approach.[Low-Beer & Stoneburner 2004] Since the emphasis on HIV prevention has shifted from the ABC's to circumcision, the incidence of HIV in Uganda is increasing. [Ministry of Health (Uganda) 2012] Statistical analysis shows that the impact of very large increases in circumcision rates can be offset by small decreases in condom use. Consequently, it is likely the circumcision programs in Africa may increase the HIV infection rates in Africa.[Van Howe & Storms 2011] The numbers needed to treat can be estimated based on the numbers already available. For example, for urinary tract infections it is between 111 and 195. [refs 106, 107] For penile cancer, it is between 4237 and 7184 (Statement 172). Since HIV has not been found to be associated with circumcision status in any of the North American studies, it is not possible to assign a number needed to treat for North America. Only the prevalence of syphilis has been shown to be associated with circumcision status, but the incidence has not, so it is not possible to assign a number needed to treat. The Task Force is calling for numbers they already have, but they do not appear to want to believe, or that will be impossible to gather.

Statement 284: "The population-based incidence of complications of newborn male circumcision (including stratifications according to timing of procedure, type of procedure, provider type, setting, and timing of complications [especially severe and non-acute complications])."

Comment: **Incomplete**. This should also include the psychological impact, impact on sexual function and satisfaction, impact on personal relationships, and impact on overall health.

Statement 285: "The impact of the AAP Male Circumcision policy on newborn male circumcision practices in the United States and elsewhere."

Comment: **Irrelevant yet unexpected**. One of the unintended consequences of the release of the 2012 Report of the AAP Task Force on Circumcision is that it helped rally European physicians, ethicists, and legal scholars to protest the human rights abuses associated with the practice. In the wake of the report's release, the Council of Europe and a number of national medical organizations in a variety of European countries have condemned the practice of newborn circumcision as a human rights violation.[Royal Dutch Medical Association 2010, Anonymous The Local 2013, Soumen Lääkäriliito 2012, Guiborg 2012, Anonymous Huffington Post 2014, Hartman 2012, College of Physicians and Surgeons of British Columbia 2004, Kendel 2002, Friedman 2011, Slovenian Human Rights Ombudsman 2012] They have found the "benefits" of circumcision to be inconsequential. When responding to a letter written by 38 leading European medical experts that characterized the Task Force as "culturally biased,"[Frisch et al 2013]

Analysis of 2012 AAP Task Force on Circumcision Report

instead of addressing the substantive issues raised, the Task Force responded with righteous indignation and issued a thinly-veiled accusation that the letter writers were anti-Semitic.[Task Force 2013] A similar response[AAP Task Force 2013] was given by the Task Force to another criticism of the report.[Svoboda & Van Howe 2013]

Some circumcision enthusiasts did not believe the report went far enough.[Morris et al 2014] The irony is that their reactionary approach backfired. When the Task Force led the charge to preserve infant circumcision, they were hoping to attract the attention of Americans and bring the Europeans, who had to that point remained silent on the issue, in line behind them. Instead, it woke up the sensibilities of the Europeans, which has now been noticed by many Americans leading them to question the practice of infant circumcision in increasing numbers. By overreacting and putting out a statement based on cultural beliefs and personal preference rather than on science, the Task Force members have embarrassed themselves, the members of the American Academy of Pediatrics, and American physicians generally. What is interesting is the pro-circumcision physicians who have infiltrated the Centers for Disease Control and Prevention tried the same tactic in late 2014 by issuing a "draft recommendation," which took seven years to develop, was short on science and execution, and it was based primarily on cultural factors. Unlike the Task Force report, a public commentary period was required for their "draft recommendations." Of the thousands of comments submitted, over 95% exposed the scholarly dishonesty of their draft.

Statement 286: "The extent and level of training of the workforce to sustain the availability of safe circumcision practices for newborn males and their families."

Comment: **True motive**. It's all about increasing the demand for circumcision, to keep the money rolling in, to legally protect current providers of circumcision, to maintain circumcision as the *status quo*, to continue dubious religious rituals, and to continue the culture of circumcision as the default cosmetic appearance in the US, thus providing cover for their inability to say they were wrong.

CONCLUSIONS

Statement 287: "This technical report provides recommendations regarding the practice of male circumcision, particularly in the newborn period. It emphasizes the primacy of parental decision-making and the imperative for those who perform male circumcisions to be adequately trained and use both effective sterile techniques and pain management."

Comment: **Unethical, inconsistent with other AAP policy**. There is legitimate debate over whether parents have the authority to give proxy consent for the procedure.[ref 9, Svoboda, Van Howe, & Dwyer 2000]

Statement 288: "The report evaluated current evidence regarding the effect of male circumcision on the prevention of STIs (including HIV), UTIs, cancer, and other morbidities. Evidence about

Analysis of 2012 AAP Task Force on Circumcision Report

complications resulting from male circumcision and the use of analgesia and anesthesia were also discussed."

Comment: **Misleading**. All of the current evidence was not evaluated. Primarily the evidence supporting circumcision was included. Complications, risks, and harms were profoundly disregarded and downplayed.

TASK FORCE ON CIRCUMCISION

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