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***Keywords**: Human Papillomavirus (HPV) is a sexually transmitted infection. It infects millions of people worldwide and kills hundreds of thousands of women by way of cervical and vaginal cancer, while also causing the rarer penile and anal cancers. The United States Food and Drug Administration (FDA), approved GARDASIL, the first vaccine to prevent the four strands of HPV (6, 11, 16, 18) that cause 70% of cervical cancers and 90% of genital warts worldwide. GARDASIL, from Merck, has been approved for females aged 9 to 26 years old and recommended by the CDC for girls 11-12 years old in hopes of providing immunity prior to sexual debut or infection. GARDASIL has been a source of much controversy, particularly concerning the idea of mandatory HPV vaccination. This paper examines the issue of mandatory vaccination for HPV with GARDASIL at this point in time and concludes it is not justifiable.*

***Keywords**: HPV, mandatory vaccination, Gardasil, principlism.*

INTRODUCTION

In July 2006, Merck received FDA approval for GARDASIL, the first vaccine for the human papillomavirus (HPV), which causes genital warts and cervical cancer. It has been touted by many as a public health triumph that will be a cost-effective means of preventing cervical cancer of which approximately 250,000 women die each year around the world.[1] There is, however, a large group opposed to the vaccine. One popular argument of those in opposition to the vaccine is rooted in the belief that widespread vaccination will have the consequence of increased promiscuity among young women. With poor sex education leading to unsafe sexual practices, such an increase in the number of partners at younger ages could lead to an elevated incidence of other sexually transmitted infections. Among these polar positions, many questions have been raised concerning the cost of the vaccine, access to the vaccine, who should get it, the quality and duration of the immunity it offers, marketing strategies and disclosure of information, and the dilemma of making the HPV vaccine mandatory for students to attend school (primary, secondary, or beyond). The goal of this paper is three-fold: 1) examine the state of HPV infection in the United States; 2) review development of GARDASIL, its clinical testing, and its approval; 3) discuss the ethical concerns of cost, access, marketing, and other implications of mandatory vaccination. The ethics of the HPV vaccine will be examined using the ethical norm of Principlism.

HPV INFECTION AND TREATMENTS

There is a variety of papillomavirus that can infect many species of animals,[2] and over 100 strains that infect humans.[3] Of these potentially infectious strains of HPV, most infect asymptomatically.[4] However, thirty different strains, classified as low or high risk, can result in genital warts or cancers.[5] These strains are contracted through sexual activity (vaginal, anal, or oral) with someone already infected.[6]

[1] Donya C. Arias, "A New Vaccine for Cervical Cancer Virus Raises Access Questions: Vaccine Approved," *The Nation's Health* 38/6 (2006): 82006.

[2] Donald G. A. McNeil, "How a Vaccine Search Ended in Triumph," *The New York Times*.

[3] "A Human Papillomavirus and Genital Warts," Health Matters B National Institute of Allergy and Infectious Diseases (National Institute of Health of the U.S. Department of Health and Human Services), accessed Aug. 14, 2006, http://www.niaid.nih.gov/factsheets/stdhpv.htm.

[4] Ibid.

[5] Ibid., 3

[6] Ibid.

Caused by low-risk strains of HPV, A[g]enital warts are soft, moist, or flesh-colored and appear in the genital area within weeks or months after infection.[7] They can be isolated or gathered in Acauliflower-like clusters that can vary in size and are either raised or flat on the skin.[8] Typically, genital warts can be found in or around the vagina, on the cervix, and in or around the rectum or anus of women.[9] In men, genital warts are usually observed on the tip or shaft of the penis, on the scrotum, or in or around the rectum or anus.[10] In some cases, these warts can also be found in the oral cavity or throat.[11]

High-risk strains of HPV can cause cancers of the Acervix, vulva, vagina, anus, or penis.[12] These cancers may or may not be detected by a Pap test.[13] [14] [15] Pap results may show what is known as squamous dysplasia,[16] [17] or abnormalities of the squamous cells, which are usually further examined by way of colposcopy and biopsy.[18] [19] Should a precancerous lesion be found, there are a few treatment modalities that can be pursued. For non-immunocompromised women under the age of 24, follow-up colposcopy and screening should be employed to monitor the lesion, while the immune systems of the women are given a chance to resolve the lesion naturally.[20] Other fairly more invasive procedures to remove the lesions include A[c]old knife conization, laser ablation, laser conization, and large loop excision of the transformation zone (LLETZ; also known as LEEP, or loop electrosurgical excisional procedure).[21] In the United States, these procedures are employed in continually growing numbers as the epidemic of HPV continues to spread at incredible rates.

According to the CDC, "[a]bout 1% of sexually active men in the U.S. have genital warts at any one time." In addition, penile cancer will be diagnosed in about 1 of every 100,000 men. For 2006, the American Cancer Society (ACS) estimated the total number of penile cancer diagnoses to be 1,530. A similar estimate of 1,900 cases of anal cancer was estimated by the ACS for 2006. The occurrence of anal cancer among bisexual and homosexual men is 17 times greater than in heterosexual men.[22]

According to Journal of American Medical Association (JAMA) from Dunne, et.al., "The overall HPV prevalence was 26.8% among US females aged 14 to 59 years." The prevalence of HPV in women aged 14-24 years old was 33.8%, which corresponds to approximately 7.5 million women of this age group currently infected with HPV. The highest rates of infection were found to be among females aged 20-24 (44.8%).[23] It is estimated that 20 million Americans currently have a genital HPV infection.[24] Furthermore, each year in the United States, there are approximately 6.2 million new genital HPV infections.[25] With genital HPV

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[7] Ibid.

[8] Ibid.

[9] Ibid.

[10] Ibid.

[11] Ibid.

[12] Ibid.

[13] Ibid.

[14] The Pap smear, or Pap test, was named for its founder George Papanicolaou, M.D. The procedure consists of collecting squamous epithelial cells from the cervix using an instrument called a speculum. The cells are prepared in a dish or slide for laboratory examination to determine if abnormal cervical cells are present. (see 15).

[15] Mayo Clinic Staff, "A Pap smear: Screening test for cervical cancer," Women's Health: MayoClinic.com, accessed 3/10/2006 at http://www.mayoclinic.com/health/pap-smear/HQ01177

[16] "A High-Grade Squamous Dysplasia and an Intraepithelial Lesion Due to HPV Infection of the Cervical Squamous Epithelium," (see 17).

[17] M. Kyrgiou, G. Koliopoulos, P. Martin-Hirsch, M. Arbyn, W. Prendiville, E. Paraskevaidis. "An obstetric outcomes after conservative treatment for intraepithelial or early invasive cervical lesions: systematic review and meta-analysis," *The Lancet* 2006; 367: 489B98.

[18] A colposcopy is an examination of the cervix, vagina, and vulva with a specialized lighted microscope called a colposcope. It is used to examine the epithelial cells of the female reproductive system for abnormal cells or lesions at high magnification. A biopsy of abnormal cells may be taken to determine the cause of any abnormalities observed. Ibid., 19.

[19] "A Colposcopy: A follow-up to abnormal Pap test results." Diagnostic Tests: MayoClinic.com., accessed 5/17/2005, at http://www.mayoclinic.com/health/colposcopy/WO00097

[20] Susie Lau and Eduardo L. Franco, "A Management of low-grade cervical lesions in young women," *Canadian Medical Association Journal*, September 27, 2005; 173 (7):771-773. accessed, doi:10.1503/cmaj.050561

[21] Ibid.

[22] "HPV and Men – CDC Fact Sheet," *Centers for Disease Control*, August 14, 2007, accessed 11 September 2007, http://www.cdc.gov/std/hpv/STDFact-HPV-and-men.htm#testforwomen

[23] E. Dunne, E. Unger, M. Sternberg, G. McQuillan, D. Swan, S. Patel, L. Markowitz, "Prevalence of HPV Infection Among Females in the United States." *Journal of the American Medical Association* 297(8): 813-819.

[24] "Sexually Transmitted Diseases: Genital HPV Infection - CDC Fact Sheet," Centers for Disease Control, May 2004, accessed 10 October 2006, http://www.cdc.gov/std/HPV/STDFact-HPV.htm

[25] Robert Steinbrook A, "The Potential of Human Papillomavirus Vaccines," *New England Journal of Medicine* 354(11):1109-1112

infections so prevalent, the CDC Advisory Committee on Immunization Practices made the recommendation that all females ages 11 and 12 be inoculated with the Merck vaccine, GARDASIL.[26]

GENERAL FDA APPROVAL OVERVIEW

The CDC recommendation came following the United States Food and Drug Administration (FDA) approval of GARDASIL on June 8, 2006. The approval came by way of a six month fast-tracked process. In accordance with FDA approval guidelines, the decision on GARDASIL was expedited Aunder FDA′s priority review process--a process for products with potential to provide significant health benefits.[27]

AFDA′s Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Current authority for the regulation of vaccines resides primarily in Section 351 of the Public Health Service Act and specific sections of the Federal Food, Drug and Cosmetic Act.[28] The process for vaccine approval, as for approval of any other drug, must be initiated by the submittal of an AInvestigational New Drug (IND) application, which includes information on the drug itself, its manufacture, quality control methods, safety measures, immune response in animal studies, and proposed protocol for human studies.[29] These clinical human studies usually consist of three separate phases.

APhase 1, are safety and immunogenicity studies performed in a small number of closely monitored subjects. Phase 2 studies are dose-ranging studies and may enroll hundreds of subjects. Finally, Phase 3 trials typically enroll thousands of individuals and provide the critical documentation of effectiveness and important additional safety data required for licensing.[30]

Throughout the various studies, should there be any safety concerns, the FDA may request additional research or directly stop research.[31] When these studies have been completed, a Biologics License Application (BLA) for the vaccine may be submitted to Athe multidisciplinary FDA reviewer team.[32] This team consisting of Amedical officers, microbiologists, chemists, biostatisticians, etc. weighs the potential benefits against the risks in an analysis of the safety and efficacy studies presented. After also performing an inspection of the manufacturing site, this team makes a recommendation for endorsement of the vaccine=s approval. At this point, the vaccine may be brought before the Vaccines and Related Biological Products Advisory Committee (VRBPAC), a multidisciplinary team of non-FDA employees to analyze the proposed vaccine and advise the FDA. Finally, for approval, an accurate and sufficient label for the vaccine must be provided to physicians for understanding of benefits, risks, and uses.[33]

Once the vaccine has been approved, the FDA continues to oversee issues of safety and efficacy. The means taken to ensure safety may include periodic inspection of the facilities, testing of each vaccine lot, and continued APhase 4 studies to monitor widespread prevalence for any indication of adverse effects.[34]

THE MERCK HPV VACCINE

GARDASIL is advertised as the world=s first and only vaccine for cervical cancer currently on the market. It protects against four strains of HPV (6, 11, 16, and 18). HPV strains 16 and 18 cause 70% of cervical cancers and HPV strains 6 and 11, although less malignant, cause 90% of genital warts. It was developed by a number of researchers working at Athe National Cancer Institute, the University of Rochester, Georgetown University, and Queensland University in Australia[35] as a recombinant vaccine, which means it contains no live virus.[36] It was designed using virus-like particles (VLPs) consisting of L1 protein particles found in

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[26] Ibid.

[27] "A FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus: Rapid Approval Marks Major Advancement in Public Health," *FDA News*, U.S. Food and Drug Administration, accessed http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html

[28] "A Vaccine Product Approval Process, "U.S. Food and Drug Administration Center for Biologics Evaluation and Research, 7/27/2002, accessed, http://www.fda.gov/cber/vaccine/vacappr.htm

[29] Ibid.

[30] Ibid. 28

[31] Ibid.

[32] Ibid.

[33] Ibid.

[34] Ibid.

[35] Ibid., 2

[36] Ibid., 28

HPV types 6, 11, 16, and 18.[37] These proteins are produced in separate recombinant Saccharomyces cerevisiae (yeast) cultures that are grown on media consisting of Avitamins, amino acids, mineral salts, and carbohydrates.[38] The self-assembled VLPs are then cultivated by disrupting the S. cerevisiae membrane.[39] After Achemical and physical purification, the VLPs are absorbed onto an Aaluminum hydroxyphosphate sulfate adjuvant.[40] The resulting sterile liquid suspension, containing the HPV type 6, 11, 16, 18 VLPs and deliverable by way of intramuscular injection, underwent four clinical trials to demonstrate safety and efficacy.[41]

In each particular trial, the prophylactic efficacy of GARDASIL was determined to be nearly 100% for each strain of HPV.[42] This means that a woman not infected by strains 6, 11, 16, or 18 at day 1 of the protocol did not become infected by those HPV strains throughout the follow-up period.[43] Furthermore, AGARDASIL reduced the overall rate of CIN 2/3 or AIS caused by vaccine or non-vaccine HPV types […], compared with placebo.[44] As compared to placebo, A[d]efinitive therapies [_] (e.g., loop electrosurgical excision procedure, laser conization, cold knife conization) and surgical procedures for treatment of HPV-related diseases were reduced by 16.5% and 26.5%, respectively.[45]

The duration of the immunity provided by GARDASIL was estimated to peak 1 month after the third dose (the three doses were given over a six month period). Over the course of two and three years, the HPV antibodies remained above baseline, but declined dramatically. AThe duration of immunity following a complete schedule of immunization with GARDASIL has not been established.[46]

Analysis of Mandatory HPV Vaccination Using the Principlist Norm of Ethics

Principlism is a product of the Belmont Report from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978),[47] which resulted in the aftermath of the Tuskegee Study of Untreated Syphilis in the Negro Male. It is used in ethical analysis by considering ethical issues in light of the primary principles of Arespect for persons, beneficence (including non-maleficence), and justice.[48] ARespect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents; and second, persons with diminished autonomy are entitled to protections.[49] Beneficence is presented as an Aobligation defined by Atwo general rules: (1) do not harm and (2) maximize possible benefits and minimize possible harms.[50] Its mandate to Ado no harm is rooted in the Hippocratic Oath. Justice refers to A>fairness in distribution= or >what is deserved.[51] This translates into the ideas of just allocation of resources and equity. Secondary principles include fidelity, veracity (truthfulness), confidentiality, and utility.[52] To apply Principlism to a case, James Childress provides Henry Richardson=s Athree main models: A(1) application, which involves the deductive application of principles and rules; (2) balancing, which depends on intuitive weighing of conflicting principles; and (3) specification, which proceeds by >qualitatively tailoring our norms to cases= (1990).[53]

The first issue to consider in mandatory HPV vaccination is how the vaccine may be used to maximize overall efficacy and safety. This invokes the questions: For whom should the HPV vaccine be made available? For whom should it be recommended?

HPV vaccine has been demonstrated to be effective in preventing HPV strains 16 and 18 typically resulting in pre-cancerous lesions or cancers in girls/women ages 9-26. This is a definite good and a result from which all people could benefit, should GARDASIL pass the appropriate safety considerations. In this light, the HPV vaccine passes the test of beneficence for women

[37] AGARDASIL, "Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18)" *Recombinant Vaccine*, Merck & Co., Inc., Whitehouse Station, NJ 08889, USA., June 2006.

[38] Ibid.

[39] Ibid., 37

[40] Ibid.

[41] Ibid.

[42] Ibid.

[43] Ibid.

[44] Ibid.

[45] Ibid.

[46] (See Table 3) Ibid., 37

[47] James F. Childress, "A Principles-Oriented Bioethics" in *A Matter of Principles?: Ferment in U.S. Bioethics*, eds. DuBose, E., Hamel, R., and Laurence O'Connel (Valley Forge, PA: Trinity Press International, 1994), 72-83.

[48] Ibid.

[49] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, D.C.: U.S. Government Printing Office, 1979), 22-28.

[50] Ibid.

[51] Ibid., 49.

[52] Ibid.

[53] Ibid., 47.

ages 9-26 on whom such studies have been completed. However, the vaccine has not been tested on girls younger than 9 or older than 26, or on boys and men. For these groups, GARDASIL's safety and efficacy are not known. This being the case, vaccination for these groups does not pass the test of beneficence. The fact that there are groups who could possibly benefit from the vaccine, but for whom the vaccine has not been tested, is a cause for considering the principle of justice as well. According to justice, those of like circumstance (in this case, risk for contracting HPV and experiencing its potentially harmful effects) should be treated in a like manner. Therefore, if GARDASIL was tested and made available to females 9-26 years old, it should also be tested and made available to males, infants and younger children, and women who can all be infected, develop cancers or warts, and potentially spread infection. Despite the inequities, women are at much greater risk for HPV-caused cancer than men.[54] [55]One inequity among women stands out, however. The prevalence of HPV infection among women aged 30-39 and 40-49 was 27.5% and 25.2%, respectively.[56] GARDASIL was not tested or approved yet for these groups, but it has been for women in the age 14 – 19 group, among whom the HPV infection prevalence is 23.3%.[57] Nonetheless, the vaccine was initially studied and recommended for many of those with the most at risk and the most potential benefit, and studies are currently being undertaken for some of those groups (boys, men, and women over 26). To this point, however, there have undoubtedly been numerous new infections among these groups which may have been prevented if they were included in the initial studies. This inequity violates the principle of justice.

The second issue to consider in mandatory widespread vaccination for HPV is the financial barrier. Is the HPV vaccination financially feasible for all those who could benefit from it? AThe present cost of screening-prevention methods like Pap smears and colposcopy approaches $6 billion a year in the United States. Those costs will continue in addition to the vaccine expense. Who will pay for cervical cancer prevention for the neediest women and girls?[58]

In order for any medical intervention to have any significant impact on public health it must be widely accessible in both cost and delivery. However, the cost of the GARDASIL, estimated to fall at about $360, is prohibitive for much of the population of the United States. With the CDC recommendation of GARDASIL in June 2006 and its addition to the Vaccine for Children (VFC) contract in November 2006,[59] [60] the cost of the vaccine for eligible 9-18 year old females will be covered as one method of helping with these concerns of cost and access. According to Merck, A[h]ealth insurers covering approximately 94 percent of privately insured lives in the US (currently more than 95 insurance plans) have decided to reimburse GARDASIL.[61] Meanwhile, Merck is doing its part by initiating a Apatient assistance program for vaccines to reduce the financial barrier to HPV vaccination.[62] With the financial assistance available in the United States through government, insurance, and corporate support, concerns of cost are being alleviated. However, despite the outward appearance of progress in gaining financial support, the reality is a complex insurance system that is Ahighly fragmented and uneven and taxing on physicians and healthcare.[63] Also, with 46 million people in the United States without health insurance,[64] the task of both Merck and the government to vaccinate widely will be difficult. This will almost certainly make the HPV vaccine not nearly as accessible as it should be, or as the public is being led to believe.

These issues of high cost and limited access to the HPV vaccine seem to place principles of beneficence and justice in conflict. None of the experts seem to dispute that a vaccine for HPV, if safe, could have tremendous health benefits, and so providing it to all persons would be medically beneficent. Despite the plans for financial sponsorship discussed above, there are still questions of how effective these programs will be, and how the vaccine will be delivered to regions with little infrastructure for education and

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[54] Ibid, 22

[55] Ibid, 23

[56] Ibid

[57] Ibid

[58] Ben Daitz, "A Vaccine Prevents Cervical Cancer. So, What's the Down Side?" *The New York Times*. 5/27/2006, accessed, http://www.nytimes.com/2006/05/23/health/23comm.html?ex=1164085200&en=9e...

[59] Since 1994, the VFC program has provided vaccines to children through age 18 who are Medicaid-eligible, uninsured, underinsured1 or Native American. After the CDC's Advisory Committee for Immunization Practices (ACIP) has made a recommendation for the use of a given vaccine, the ACIP votes on whether the vaccine should be included in the VFC program. At the June 2006 meeting of the ACIP, the committee voted unanimously to recommend GARDASIL to the VFC program. Eligible adolescents may receive recommended vaccines through VFC once the CDC contracts for the purchase of the vaccine, a process that is now complete. See 63.

[60] Americk's Merck's Cervical Cancer Vaccine, GARDASIL 7, added to the CDC Vaccines for Children Contract," *Merck Newsroom: Product News*, 11/1/2006, accessed http://www.merck.com/newsroom/press_releases/product/2006_1101.html

[61] Ibid

[62] Ibid, 60.

[63] Giffin, R., Stratton, K., and Rosemary Chalk, "A Childhood Vaccine Finance and Safety Issues," *Health Affairs* 23(5):98-111, 9/9/2004, accessed, http://www.medscape.com/viewarticle/488339

[64] "A Health Insurance Coverage," National Coalition on Health Care, accessed at http://www.nchc.org/facts/coverage.shtml

distribution. Given the long span of time over which the vaccine must be given, there may be concerns that patients will not adhere to the vaccine administration schedule and return for the second and third doses. In addition, it seems unlikely that programs initially in place to overcome these obstacles of cost and access will be sustained to provide the second and third shots.

In this context, it is also important to consider the issue of just allocation of resources. Should we spend what is estimated to be billions of dollars on mandating a vaccine for cancers that are reduced in prevalence each year in the United States with proper screening techniques? Would those billions of dollars be better spent on diseases that affect more Americans? Perhaps those billions of dollars could be spent on other effective preventative measures like education programs and more available, affordable, and comprehensive screening programs. There is also the alternative of condom distribution that could impact more widely on HPV[65] and other STIs. It simply does not seem that the CDC's recommendation of vaccinating all girls in the US ages 11-12 for disease that could be prevented in most cases by proper education and screening programs is the best use of the government=s health care budget when 46 million Americans are not insured[66] and even more do not have adequate access to healthcare.

A third issue is Merck=s marketing and education plan, as well as Merck's lobbying for mandatory vaccination. The advertisements inspire the question of whether or not Merck has been open in educating women in the benefits of GARDASIL, as well as the limitations and alternative modes of prevention. Merck's lobbying campaign to state legislatures and other politicians for mandatory school vaccinations, even prior to GARDASIL's FDA approval, were a cause for concern among many.[67] This issue is relevant in this discussion in its relation to the motivation or intent of a mandatory vaccination program and is important in determining if health of people is the primary objective of this vaccine and the push for mandatory vaccination. Is Merck misleading the public through its marketing campaign? Were there hidden motives to Merck's intense lobbying campaign aside from the interests of public health?

Merck advertises GARDASIL as a cervical cancer vaccine, but also states that it does not protect against all cervical cancers. Merck's One Less commercials and marketing campaign of GARDASIL also include recommendations for screening. What the commercials fail to discuss is how one can be infected by HPV. Also, questionable is Merck=s inclusion of HPV strains 6 and 11, which can cause genital warts. Merck=s strategy of marketing GARDASIL as a means to being Aone less statistic of cervical cancer does not really justify the vaccine=s inclusion of HPV strains 6 and 11. In this sense the commercial seems to be somewhat misleading to women. It seems as though this marketing campaign intends to play on women=s fears of cervical cancer and genital warts as a means of convincing women to get the vaccine, even if they are not at great risk. Merck, however, is a business, and understandably uses marketing to increase consumer demand for its product. Regardless, Merck is increasing awareness of HPV-caused cancers, and one effective mode of prevention for women aged 9- 26, vaccination with GARDASIL.

In addition to the "one less" marketing campaign, Merck has spent considerable efforts in lobbying state legislatures and politicians for mandating the vaccine for girls' attendance in schools. In Texas, Governor Rick Perry, did just that by way of an executive order, while such a mandate has been considered in more than 20 state legislatures. Although the Texas Governor's executive order was eventually overturned by the state legislature, it brought up significant questions of Merck's lobbying, which in Texas was represented by Michael Toomey, the chief of staff for Gov. Perry from 2002-2004.[68] Some people have questioned the motivation behind the mandatory vaccination lobbying campaign as a profit-seeking venture by Merck, who has been plagued in recent years by settlements and drug recalls like Vioxx. Others simply questioned the safety in mandating such a new vaccine, in light of recent recalls for drugs that were FDA approved, but were later found to be unsafe. In response to such concerns and as a result of outcry sparked by Gov. Perry's executive order, Merck announced it would cease its lobbying efforts to avoid their becoming a "distraction" to prevention of cervical cancer.[69]

Dr. Richard M. Haupt, executive director for medical affairs in Merck's vaccine division, has claimed "Our goal is to prevent cervical cancer."[70] If it is true that Merck is attempting to make each woman (or man) "one less" statistic, their advertising campaign should truthfully educate women and men as to alternative forms of HPV prevention, thus reducing the incidence of cervical and other HPV-caused cancers. Meanwhile, the safety and effectiveness of the vaccine over time would prompt state legislatures to mandate the vaccine on its merit.

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[65] Rachel L. Winer, Ph.D., James P. Hughes, Ph.D., Qinghua Feng, Ph.D., Sandra O'Reilly, B.S., Nancy B. Kiviat, M.D., King K. Holmes, M.D., Ph.D., and Laura A. Koutsky, Ph.D. "A Condom Use and the Risk of Genital Human Papillomavirus Infection in Young Women," *New England Journal of Medicine*, 354 (25): 2645-2654. June 22, 2006, accessed 10/18/2006, http://content.nejm.org/cgi/content/full/354/25/2645

[66] Ibid., 64.

[67] Pollack, Andrew and Stephanie Saul. "Merck to Halt Lobbying Vaccine for Girls." *The New York Times*, February 21, 2007, accessed http://www.nytimes.com/2007/02/21/business/21merck.html?ex=1329714000&en...

[68] Blumenthal, Ralph. "Texas Legislators Block Shots For Girls Against Cancer Virus." *The New York Times*, April 26, 2007, accessed http://query.nytimes.com/gst/fullpage.html?sec=health&res=9A0DEEDE153EF9...

[69] Ibid. 67

[70] Ibid.

Finally, the issue of mandatory vaccination must be considered. It is important that all of the ethical issues discussed above be taken into consideration when determining whether or not HPV vaccination should be made mandatory for attendance at school, and, if so, for whom and for what level of schooling should it be mandatory.

Based on the principle of beneficence in the current circumstances (sexual activity and sexual transmission of infection is a widespread reality, the vaccine has already been developed, and it can save lives) the vaccine should be made available to those who may benefit from it, assuming that it is demonstrated to be safe and effective in the long-term. However, the vaccine should only be administered in conjunction with a comprehensive education and screening program. If we are prepared to fund vaccinations, we should also be capable of funding the very effective preventive measures of education and screening that will enable sustainability in a preventive health effort.

The CDC currently recommends that the HPV vaccine should be given to all girls 11-12 years old. Many of those in this recommended population, unfortunately, cannot afford the three dose regimen of GARDASIL. In addition, there are other groups at similar risk of being infected and spreading HPV for whom the vaccine has not been studied or recommended. The principle of justice would demand the vaccine be made available in a like manner for those of like circumstances, regardless individual financial capabilities. Given the cost of the vaccine, the issues of accessibility, and the already inflated health care spending in the U.S., mandatory vaccination for students to attend school is unjustifiable. Should the vaccine not be fully funded by the government, it will create an even greater gap between the rich and poor of the U.S. Those who cannot afford vaccination will have a much greater chance of developing HPV-caused cancer. This health disparity will continue to further delineate the gap between rich and poor and cause more severe injustice. Should the vaccine be fully funded by the government, a tremendous strain will be placed on state and federal budgets and a further inflation of health care spending in the U.S. Consequently, funding to other programs would have to be cut or taxes would have to be increased substantially. Meanwhile, the number of uninsured Americans would continue to increase and while a few thousand Americans would be saved from cervical cancer, many more could, instead, face a shortened life of untreated chronic infection.

Despite the good intentions of HPV vaccine proponents to prevent a disease that kills hundreds of thousands worldwide, widespread HPV vaccination in the U.S. is simply a technological patch on a much larger problem of inadequate education, screening, and alternative prevention programs. Although, making the HPV vaccine available would be both beneficent and just, making it mandatory seems to violate justice and autonomy. Other justice-related issues of making vaccination mandatory in the United States lead to questions of our responsibility to provide the vaccine internationally to those most vulnerable, especially to those in developing nations where there are much higher rates of cervical cancer deaths, and there is less access to screening and preventive measures.

CONCLUSION

Based on the above analysis of the ethical questions surrounding this topic, this paper contends that mandatory vaccination for any population should not be pursued. This decision is primarily based on the principle of justice. Making HPV vaccination a mandatory requirement for attendance in school without government funding would lead to further inequity among the wealthy and poor of the U.S. Doing so with government funding, will overtax government budgets while failing to address the root causes of deaths due to cervical cancer, access to healthcare. Given the limited resources of our country and the world, there are better alternatives for reducing cervical cancer incidence and mortality besides GARDASIL at this point. These include education, condom distribution, regular visits to a physician, and routine Pap tests. However, should a less expensive, more easily deliverable, and equally safe and effective vaccine for HPV be developed, the question of mandatory HPV vaccination should be reconsidered.

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