

THE FOUNDATION FOR HPV AND ANAL CANCER
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Testimony before the Vaccines and Related Biological Products Advisory Committee
Food and Drug Administration
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Members of the committee, thank you for the opportunity to testify today. My name is Justine Almada and I am a member of the board of The Foundation for HPV and Anal Cancer, a non-profit, nonpartisan organization that I co-founded with my two siblings. I am here with my sister, Camille Almada, also a member of the board.

Our organization aims to educate the public about anal cancer, to address the stigma associated with the disease, to advocate for prevention and improved early screening methods, to provide resources for patients, caregivers and members of the scientific and medical communities, and to invest in research for therapeutic treatments. No entity, including Merck, has influenced our comments or paid for our travel to be here today. We hope our efforts will lead to improved patient knowledge, choices, quality of life and survival. The approval of the anal cancer indication for the HPV vaccine for both men and women is one of many tools to advance these efforts.

We lost our mother seven months ago to stage IV anal cancer. She was asymptomatic, exercised regularly and ate well when she was diagnosed in March 2008. She had raised three children and was about to embark upon a career change that focused on her passions. Instead, at the age of 51, she began a two-year marathon that ended in her tragic death.

Our mom was a vivacious, beautiful and dedicated woman - the type of mom who would help you with your homework, support you when you made a mistake, work hard to make sure her kids were clothed, fed, housed and educated, and was always the life of the party. She faced her diagnosis with emotional and physical strength. She continued to work, and pursued a masters degree program at night, while enduring chemotherapy, until the last three months of her life.

Over 5,000 people a year are diagnosed with anal cancer - some like my mom, and some different - yet

the vast majority of these cases are caused by the human papillomavirus (HPV). We commend the steps the FDA has already taken to aid in the reduction of HPV-associated cancers in girls by approving the HPV vaccines, Gardasil and Cervarix, for the prevention of cervical, vulvar and vaginal cancers. We strongly urge you today to approve expanding the Gardasil indication to include prevention of anal dysplasia and anal cancer in both females and males.

The physical strain of fighting anal cancer is arduous and the emotional burden is severe. The body endures toxic chemotherapy drugs, causing prolonged fatigue, extreme nausea, and debilitating chronic pain. Radiation to a very sensitive part of the body can cause diarrhea, changed sexual functioning, extreme burns, bleeding and long-term gastrointestinal complications. Some patients require body-changing ostomies.

While those suffering with anal cancer endure a physical battle with toxic chemotherapy and radiation, it is hard to think of a cancer with a more oppressive social stigma. People are afraid to say the very words "anal cancer," to openly discuss it and to share the experience of this illness with the ones they love. Our mother felt this way, hiding her cancer from others because she was afraid of being judged. Not only does anal cancer affect a part of the body uncomfortable for some people to talk about, but it is associated with sexual practices. Anal HPV can be found in any individual who has been sexually active, and anal cancer can manifest itself in those who have a compromised immune system, who smoke, or who have had previous cervical dysplasia.

Anal cancer can affect a person's quality of life from its Anal Intraepithelial Neoplasia or anal precancer stages. Patients who have persistent anal precancer need to be closely monitored and often have to return for multiple treatments, which are frequently uncomfortable. The data presented today shows that the majority of anal precancer could be prevented with the HPV vaccine, but the FDA has not yet had occasion to take this step to protect men and women. You have that opportunity today. By approving the anal cancer indication for the vaccine in both young men and women, you would actively decrease the impacts of this painful disease.

Everyone deserves protection from cancer. In the men-who-have-sex-with-men (MSM) population, the need for this vaccine is great. HIV-negative MSM are seventeen times more likely to develop anal cancer. For men and women with compromised immune systems, including people living with HIV and AIDS, the rates of anal cancer development are higher and the need for the vaccine is even more pronounced.

Promisingly, the study discussed today shows that Gardasil decreases the chances that HIV negative MSM obtain an HPV infection by 78%. But this vaccine should be recommended for approval in all boys as MSMs may not self-identify until sexual activity has already commenced. Furthermore, if all boys are similarly vaccinated (regardless of sexual orientation), the number of women who encounter these cancers through sexual activity will decrease. As you have already recognized through your approval of the HPV vaccine for girls, women should be able to be protected from HPV cancers and their precursor dysplasia. The study illustrates that the similar natural histories of HPV infection in men and women indicate the vaccine will also be effective in preventing anal precancer and cancer in women.

Unfortunately, significant progress for those facing advanced disease, as our mother did, has not been made for decades. For those who do have to fight anal cancer, we will continue to support research into more innovative and effective treatments. At the same time, we believe there is a great deal more that can be done to prevent people from having to experience the battle with anal cancer at all, including making HPV prevention more accessible to more populations. According to the American Social Health Association, 75% of United States citizens between the ages of 15 and 49 have been infected with a genital HPV in their lifetime. HPV causes cervical, anal, vulvar, vaginal, penile and head and neck cancers and recurrent respiratory papillomatosis.

We applaud the FDA for approving the HPV vaccine for girls for cervical, vulvar and vaginal cancer and for boys and girls for genital warts. This vaccine should be available to both men and women as a preventative measure just as it is currently available to women for genital tract HPV-associated malignancies.

The approval of the anal cancer indication for the HPV vaccine will offer a new method to prevent a painful diagnosis and death from a disease in which significant progress in treatment has stagnated for decades. It will protect a vulnerable population made more so by the stigma associated with anal cancer. And it will logically extend the commendable work the FDA has undertaken in vaccinating women from HPV and the diseases associated with it. The incidence of anal cancer in the United States is currently growing and therapeutic measures to treat patients are not improving. That is why we are here today. We urge you to approve the indication for all boys and girls in the effort to prevent anal precancer and cancer and its consequences.