MedicalXpress

Regulatory clearance opens the way for new single-size contraceptive diaphragm in the US

September 9 2014

The United States Food and Drug Administration (USFDA) has cleared the Caya contoured diaphragm for marketing in the United States, bringing women one step closer to a new option for safe and effective non-hormonal contraception. The Caya contoured diaphragm is expected to be available to US consumers within the next year. Its clearance by the USFDA is also important for increasing women's access to non-hormonal contraceptive options worldwide because USFDA approval is a gold standard of regulatory approval globally. The USFDA decision follows approval of the Caya contoured diaphragm by European and Canadian regulatory authorities in 2013 and early 2014, respectively.

The Caya contoured diaphragm—called the SILCS Diaphragm during design and clinical validation stages—was developed by PATH, CONRAD, and partners at multiple sites through a user-centered process. Feedback from women, their partners, and health care providers from four countries helped refine the design and resulted in special features that make this single-size non-latex diaphragm simple to provide and easy to use. In clinical studies comparing the SILCS Diaphragm to a traditional diaphragm, women preferred the SILCS Diaphragm for its ease of handling. A recent contraceptive effectiveness study implemented by CONRAD confirmed the SILCS Diaphragm was as effective as a traditional diaphragm when each is used with contraceptive gel. The development and testing of the SILCS Diaphragm was supported with funds from the United States Agency for International Development (USAID) and private foundations.

In 2010, PATH licensed the SILCS Diaphragm technology to Kessel medintim GmbH (Kessel), a privately held German company that manufactures and distributes sexual and reproductive health products. Kessel now markets the SILCS Diaphragm as the Caya contoured diaphragm in 14 European countries and Canada via family planning providers, pharmacies, and online shops. With USFDA clearance, Kessel will seek a distribution partner to introduce the Caya contoured diaphragm in the United States through family planning providers. PATH and its partners are working to bring the Caya contoured diaphragm to developing countries as well.

"This approval represents a significant and hard-earned milestone in the global effort to expand women's contraceptive options," said Steve Davis, PATH president and CEO. "It demonstrates the best of what multi-sector collaboration can achieve when we harness our shared expertise to develop solutions that can improve the health of women and their families around the world."

CONRAD conducted clinical studies that validated the safety, acceptability, and effectiveness of the Caya contoured diaphragm for women, helping facilitate US market clearance. "Thanks to the unique design, it fits most women, and a pelvic exam is not required for a fitting, thus making access to this new option for birth control much easier," said Gustavo Doncel, MD, PhD, Scientific and Executive Director of CONRAD. "CONRAD has a long history of collaborating with organizations like PATH to create new methods of contraception and HIV prevention for women."

Ellen Starbird, Director of USAID's Office of Population and Reproductive Health: "USAID has supported the SILCS Diaphragm from the early days of its development, and we are pleased to see this new contraceptive technology cleared for marketing by the USFDA. We see new technologies, like the SILCS Diaphragm, as essential to meet

global family planning goals, including reaching 120 million more women and girls with family planning information and services by 2020."

Worldwide, there are many reasons why women who do not want to become pregnant are not using existing contraceptive methods. These include concerns about the side effects of hormonal contraception, preference for a method that can be used only when needed, and challenges with negotiating condom use with partners. Furthermore, women often have difficulty reaching a health care provider to discuss, initiate, or maintain other methods. The Caya contoured diaphragm could help address the needs of these women.

"This woman-initiated, non-hormonal contraceptive barrier method has great potential to improve women's reproductive health options by addressing several of the reasons for unmet contraceptive need," said Judy Manning, of the team for contraceptive research and development at USAID. Manning added that the device may fill another needed role by "serving as a delivery method for gels that help protect against HIV and other sexually transmitted infections—it could be our first true multipurpose prevention product."

The innovative single-size diaphragm was developed to expand women's options for non-hormonal barrier contraception, especially in developing countries where diaphragms are not available. PATH and its partners recognize that US consumers may also be interested in an improved diaphragm designed for ease of use and comfort, and USFDA market clearance helps pave the way for future availability.

"It is vitally important to expand access in the United States to methods that expand women's pregnancy and STI prevention options," said Wayne C. Shields, President and CEO at the Association of Reproductive Health Professionals (ARHP). "ARHP supports the

availability of as many safe, effective prevention options as possible, since each woman's sexual and reproductive health needs are unique and vary over her life span."

Provided by PATH