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Immune to Life

The Unethical Nature of Antifertility Vaccines

Andrew S. Kubick

Abstract. Antifertility vaccination is a proposed method of contraception that induces infertility through an immunological response to specific reproductive targets. The following essay analyzes several peer-reviewed articles to identify these potential targets and then determines the bioethical implications of vaccine use through the lens of Thomistic personalism. Vaccines that intentionally utilize a contraceptive action violate the principles of totality, integrity, and inseparability; while vaccines that intentionally utilize a contragestive action additionally violate the principles of inviolability of human life and nonmaleficence. An exception may exist in cases where application is directed at the treatment of specific pathologies. These cases may be tolerated using the principle of double effect when certain conditions are met. Furthermore, the safeguarding of informed consent may prove problematic if contraception is integrated with established vaccine programs. *National Catholic Bioethics Quarterly* 15.4 (Winter 2015): 639–648.

In the spring of 2014, the Kenya Catholic Doctors Association obtained samples of a tetanus vaccine during an immunization campaign sponsored by the World Health Organization (WHO) and United Nations Children's Fund (UNICEF), which had

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been launched in October of the preceding year.[1] The association expressed concern that the targeted age-group, the gender specificity of recipients, and the uncharacteristic booster regimen mirrored past tetanus vaccination programs in Mexico (1993), Nicaragua (1994), and the Philippines (1994) that had allegedly, without informing the public, used a tetanus vaccine containing beta-hCG, a subunit of human chorionic gonadotropin hormone, which can provoke an immunocontragestive effect.

Laboratory tests performed by four unrelated laboratories on behalf of the association identified beta-hCG in the provided samples. Shortly thereafter, both the association and the Kenya Conference of Catholic Bishops voiced serious concerns about the purpose of the immunization campaign and the culpability of those responsible for its execution. To this end the Kenyan bishops stated, "We are convinced that [the campaign] is indeed a disguised population control programme."[2]

In response to this serious allegation, WHO and UNICEF released a joint statement expressing their "deep concern about the misinformation circulating" regarding the Kenyan immunization campaign. The organizations vehemently denied the charge on the basis of the lack of substantial evidence. They questioned both the suitability of the laboratories that carried out the tests and the quality of the samples themselves. Furthermore, WHO and UNICEF pointed out that the purpose of the campaign was to immunize girls and women, especially pregnant mothers and their infants, who are at high risk of dying from tetanus-related complications, thus addressing the concerns raised about the logistics of the program.[3]

Acknowledging the tremendous effect immunization campaigns have in protecting the health and well-being of countless people throughout the world, and with a determined effort to avoid speculation, the following essay does not investigate the specific concern raised in Kenya by the bishops but commits to a general examination of antifertility vaccines per se. The Kenyan case, if nothing else, mandates such an inquiry. What are antifertility vaccines? How do they function? If they have potential for development, what are the bioethical implications of their use?

Antifertility Vaccines

Immunology was first recognized for its potential to prevent disease through the contributions of Edward Jenner and Louis Pasteur. Jenner, who discovered the capacity of the *Vaccinia* virus to inoculate populations against smallpox, received the

[1] Wahome Ngare, "Catholic Doctors Speak: Tetanus Vaccination Campaign Is All about Population Control," *AfricaFIAMC,* November 6, 2014, http://fiamcafrica.blogspot.com/2014/11/kenya-catholic-medical-association.html. This letter from Dr. Ngare was written "for and on behalf of the Kenya Catholic Doctors Association."

[2] John Njue, Statement by the Kenya Conference of Catholic Bishops on Mass Tetanus Vaccination Campaign Carried Out in Kenya in March and October 2014, *Kenya Conference of Catholic Bishops,* news release, November 6, 2014, http://www.kccb.or.ke.

[3] Custodia Mandlhate and Pirkko Heinonen, "Statement from WHO and UNICEF on the Tetanus Vaccine in Kenya," *UNICEF: Kenya,* November 13, 2014, http://www.unicef.org/. Dr. Mandlhate is the WHO representative in Kenya, and Dr. Heinonen is the UNICEF acting representative in Kenya.

honorary title "Father of Immunology" and consequently changed the landscape of preventive health care.[4] Decades later, Pasteur continued to investigate the genesis and function of disease, resulting in the discovery of "germ theory" and the development of vaccines against anthrax and rabies.

With the proliferation of vaccines, improvements in medical efficacy, and increased access to clean water and sanitation, the global population grew rapidly as mortality decreased. In a perverse distortion of the good intentions of Jenner and Pasteur, and in response to the success of Karl Landsteiner and Serge Metchnikoff to elicit an antibody response in animals following a hetero-species sperm injection, scientists began to suggest that it might be possible to inoculate a person against pregnancy, thereby reducing fertility and arresting what some viewed as overabundant reproduction.[5] A recent article adequately expressed the sentiment that drove such research: "Overpopulation is one of the greatest problems of the world, which if not taken into consideration, will be a serious threat for future generations."[6]

Following years of research and experimentation, in 1929, Morris Baskin "used human sperm to produce reversible sterilization in fertile women."[7] A patent for this spermatozoa vaccine was issued eight years later. Research on sperm immunization continued to gain momentum while also prompting investigations into other potential targets—for example, gametogenesis, gamete function, and post-zygotic developing human beings.[8] The idea was to "take a component of the reproductive system, put it into a vaccine vector, and then use this vaccine to block the component's activity by means of antibodies or other immunological effects or mechanisms."[9]

Gametogenesis was considered a suitable target for immunocontraception given the assumption that sterility would naturally result from the neutralization of reproductive hormones. Scientists have made attempts to elicit an immunological response by attacking the hypothalamic gonadotropin-releasing hormone (GnRH)—a hormone structurally identical in both males and females—which, in turn, would arrest the synthesis and secretion of the follicle-stimulating hormone (FSH) and luteinizing hormone (LH).[10] Data collected through mammalian experimentation

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[4] Charles A. Janeway et al., *Immunobiology: The Immune System in Health and Disease*, 4th ed. (London: Current Biology Publications, 1999), 560.

[5] Rajesh K. Naz, "Contraceptive Vaccines: Success, Status, and Future Perspective," *American Journal of Reproductive Immunology* 66.1 (June 6, 2011): 5–12.

[6] Behnam Vafadari, Yalda Khoshbakht, and Afshin Khoshbakht, "Immunocontraception Stimulation Advantages versus Other Fertility Control Methods," *Indian Journal of Medical Sciences* 67.7 (July–August 2013): 155–160.

[7] Ibid. Naz referenced the following article for this citation: Morris J. Baskin, "Temporary Sterilization by Injection of Human Spermatozoa: A Preliminary Report," *American Journal of Obstetric Gynecology* 24.6 (December 1932): 892–897.

[8] Ibid.

[9] Bogdana Stoyka, Alina Domagala, and Maciej Kurpisz, "Molecular Targets for Immunocontraception," *Archivum Immunologiae et Therapiae Experimentalis* 51.1 (2003): 45–49.

[10] A. Jagannadha Rao, "Is There a Role for Contraceptive Vaccines in Fertility Control?," *Journal of Biosciences* 26.4 supplement (November 2001): 425.

revealed a delay in "sexual maturation in adolescent animals, causing gonadal atrophy in adults."[11]

Further experiments purported reversible infertility in white-tailed deer following an injection with an immunocontraceptive targeting GnRH that lasted up to two years without requiring a booster.[12] Limitations to this method include the need for adjuvants and conjugation with a carrier—for example, tetanus toxoid (TT) or diphtheria toxoid (DT)—due to GnRH's classification as a "self" hormone.[13] Impotence has also been reported.[14] The immunocontraceptive action of GnRH vaccines in humans has failed to meet requirements for specificity, safety, and efficacy[15] but has found a potential application as a treatment for "prostatic hypertrophy and carcinoma."[16]

The next suitable target for immunocontraception has been the neutralization of the pituitary gland's FSH and LH, which would effectually "impede [hormonal] action on the [ovaries and testes] and thus interfere in the maturation of oocytes and spermatozoa."[17] FSH assists in the growth of ovarian follicles and the maintenance of spermatogenesis. Some scientists consider this a promising method.[18] LH has also been investigated because its triggering of ovulation and testosterone synthesis are indispensable for reproduction. Targeting either hormone, however, has considerable drawbacks. FSH, for example, requires the application of alternate contraception until the titre level reaches immunogenicity, and also the need for periodic boosters. Moreover, mammalian subjects receiving an immunocontraceptive targeting FSH have displayed a variability in immune response.[19] LH, on the other hand, has shown potential to negatively affect sex steroids.[20] Leading up to 1998, a total of three phase I clinical trials had been conducted on FSH and LH antifertility vaccines.[21]

Provided GnRH is allowed to initiate the release of FSH and LH, the expected effect would be the maturation and availability of functioning gametes—oocytes and spermatozoa. Research on zona pellucida antigens has indicated infertility induction through "antibody-mediated inhibition of zona/sperm receptor sites" and "cytotoxic T cell–mediated destruction of developing ovarian follicles."[22] Strong

[11] Stoyka et al., "Molecular Targets for Immunocontraception," 47.

[12] Ibid.

[13] A. Jagannadha Rao, "Contraceptive Vaccines: Current Status," *Current Science* 100.5 (January 2009): 664.

[14] Rajesh K. Naz, "Contraceptive Vaccines," *Drugs* 65.5 (April 2005): 600.

[15] Rao, "Contraceptive Vaccines: Current Status," 667.

[16] Naz, "Contraceptive Vaccines," 600.

[17] Stoyka et al., "Molecular Targets for Immunocontraception," 45.

[18] Rao, "Is There a Role for Contraceptive Vaccines in Fertility Control?," 426.

[19] Rao, "Contraceptive Vaccines: Current Status," 666.

[20] Naz, "Contraceptive Vaccines," 595.

[21] Sanjay Kumar, "Research into Antifertility Vaccine Continues despite Protests," *Lancet* 352.9139 (November 7, 1998): 1528.

[22] Stoyka et al., "Molecular Targets for Immunocontraception," 46. The authors referenced the following article for this citation: M. P. Bradley et al., "Vaccines for Fertility Regulation of Wild and Domestic Species," *Journal of Biotechnology* 73.2–3 (August 1999): 91–101.

immune responses have been elicited from a number of animal species including rabbits, dogs, and nonhuman primates, specifically through the targeting of ZP1, ZP2, and ZP3 glycoproteins.[23] Other antigens continue to be researched; however, evidence suggests such immunocontraception can cause autoimmune oophoritis and destruction of ovarian follicles.[24]

Numerous sperm-surface antigens have also been investigated for immunocontraceptive potential. Fertilization antigen-1 (FA-1), for example, restrains sperm junction. Testis-specific antigen-1 (TSA-1) restrains sperm junction as well as the reaction of acrosomes and capacitation. S-19 functions through sperm agglutination and SP-15 by disarranging sperm–egg operation.[25] Likewise, sperm equatorial segment protein (SPESP) and testicular-type human nuclear autoantigen sperm protein (tNASP) are believed to be "unique and exciting molecules ... for developing a contraceptive vaccine."[26] While past investigations into vaccines targeting gamete function in humans have favored sperm-surface antigens, a 2011 journal article recognizes "twenty-two vaccines—11 each for sperm and oocytes—[as being] under development."[27]

Finally, scientists have targeted the post-zygotic stage of development immediately following sperm–egg fusion. Among the various hormones associated with this stage, human chorionic gonadotropin (hCG) remains "absolutely essential for the maintenance of pregnancy" by stimulating progesterone production, which sustains the endometrium and facilitates implantation.[28] This antifertility vaccine differs markedly in its contragestive activity from those targeting gametogenesis and gamete function. hCG is not a pituitary hormone, though its alpha (α) subunit is common to FSH and LH. Therefore, scientists have investigated a specific target in the beta (β) subunit in order to avoid any cross-reactivity with FSH and LH, while still offering immunogenicity against pregnancy.[29] Autoreactivity is attained through a conjugation method with a carrier—for example, TT or DT.[30]

By 1994, beta-hCG-TT—along with a complimentary vaccine utilizing a heterospecies dimer (HSD-TT)—had undergone phase I and II clinical trials with proven efficacy in the majority of participants.[31] The phase II trial, in particular, was

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[23] Ibid.

[24] Rao, "Contraceptive Vaccines: Current Status," 665.

[25] Vafadari et al., "Immunocontraception Stimulation Advantages," 158.

[26] F. Xue et al., "Developing a Polyvalent Chimeric Peptide Contraceptive Vaccine" (abstract), in "Abstracts of the Third International Conference on Reproductive Immunology, 28–30 September 2013, Shanghai, China," supplement, *American Journal of Reproductive Immunology* 70.s1 (November 2013): 18.

[27] Rao, "Contraceptive Vaccines: Current Status," 665.

[28] Stoyka et al., "Molecular Targets for Immunocontraception," 47.

[29] Shilpi Purswani, N.K. Lohiya, and G.P. Talwar, "Possibility and Potential of a Vaccine against Human Chorionic Gonadotropin for Family Planning," *Current Science* 99.2 (July 25, 2010): 169.

[30] Janeway et al., *Immunobiology*, 595.

[31] Purswani, "Possibility and Potential of a Vaccine," 169. The authors report that the heterospecies dimer was a combination of hCGβ and ovine α subunits.

conducted on 148 women of proven fertility who were sexually active. Immunogenicity was reported in 119 participants once titre levels reached the bioneutralization capacity of 50 ng/ml. With only 60 percent of the cohort sustaining immunogenicity for three months or longer, periodic boosters became necessary. The resultant infertility was proven by one recorded pregnancy in 1,224 cycles. All participants continued to have normal menstrual cycles and experienced a return of fertility upon booster cessation.

Scientists examined the data for shortcomings and found a need for further investigation to improve titre induction and reduce the need for alternative contraceptive methods—most often intrauterine devices—until the recipient is rendered immunogenic.[32] With over a decade passing since this phase II clinical trial, "research and development on the hCG vaccine was revived under an Indo-US program with a grant from the Department of Biotechnology (India) in 2006" that "enabled the making of a recombinant vaccine consisting of hCGβ linked at C-terminal to a β subunit of heat labile enterotoxin of *E.coli*."[33] As of 2008, India's National Institute of Immunology was in phase III clinical trials for the hCG-TT vaccine.[34] In addition to its contragestive quality, the hCG vaccine has shown therapeutic potential in treatment against hCG-secreting tumors.[35]

Principled Critique

Interest in obtaining a state of infertility through an immunological response targeting natural hormones and biological entities has been well established throughout the past century. Despite varied success in research and numerous obstacles left to overcome, it is reasonable to conclude that scientists will continue to investigate this novel method of contraception and contragestion. Therefore, bioethicists are obliged to consider the nature of the vaccine per se and identify what principles, if any, are violated by its application.

The following critique begins with a reaffirmation of the intrinsic value of the human person from which all principles derive—specifically the principles of totality, integrity, and inviolability of human life. The body is an aspect of a unified human person. An organism composed of complex and diverse organic systems—a "little world" so to speak—directed toward the development, fitness, propagation, and survival of man.[36] It is "the richest, most independent, and most active form of life, at the highest level of the kingdom of living things and the peak of the natural history of the universe" because it unites with an immaterial, rational form, engendering a

[32] Ibid., 174.

[33] Ibid.

[34] Y. Madhavi, "Human Vaccine Science and Technology Status in India," *National Institute of Science, Technology, and Development Studies*, 2008, http://www.nistads.res.in/indiasnt2008/t4industry/t4ind20.htm.

[35] Naz, "Contraceptive Vaccines: Success, Status, and Future Perspective," 4.

[36] Thomas Aquinas, *Summa theologiae* Suppl. III.91.1.

truly unique personal being.[37] Aristotle recognized the totality of this union through act and potency suggesting that "the body is human in all its parts inasmuch as it is informed by the soul; the soul actualizes the body and makes it a human body."[38] St. Thomas Aquinas, reflecting on the supposition of the Great Philosopher, stated that "the intellect which is the principle of intellectual operation is the form of the human body," and this form is substantially present in each part by "totality of perfection and of essence."[39] Given the ontological nature of a personal being, natural moral law requires physical integrity—that is, the order and function of the body and its systems—to be respected and not unduly compromised.[40]

The application of antifertility vaccines that *intentionally* utilize a contraceptive action violate both the totality and integrity of the recipient. The neutralization of healthy, properly functioning hormones or the decapacitation of the gametes' natural role in fertilization is tantamount to an illicit act of mutilation because it is "an act that injures or impairs bodily integrity."[41] As Aquinas wrote with regard to justice, but applicable to this study as well, "so long as a member is healthy and retains its natural disposition, it cannot be cut off without injury to the whole body."[42] So too did St. Francis de Sales note in his *Treatise on Divine Love*: "We see that when life is injured in any one of the members it is weakened in all the rest. If a man's foot or arm be hurt all the body is troubled, excited, disturbed and affected; if the stomach is disordered, the eyes, the voice and the whole countenance show the effects of it, so great is the sympathy amongst the organs of man's natural life."[43] While there may be sufficiently just reasons to permit bodily mutilation of healthy members in cases of organ donation, such reasons are irreconcilable with the employment of antifertility vaccines.

The application of antifertility vaccines that *intentionally* utilize a contragestive action contravene the inviolability of human life as well as the principle of nonmaleficence—more specifically, "Do no harm." The premise of this assertion rests on the engendering of a new human being at the moment of sperm–egg fusion. This singular event marks the genesis of a one-celled human organism—the zygote—whose composition is wholly unique from his parents and whose behavior is coordinated in a manner that preserves his life, health, and continued development.[44] At this point,

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[37] Elio Sgreccia, *Personalist Bioethics: Foundations and Applications,* trans. John A. Di Camillo and Michael J. Miller (Philadelphia: National Catholic Bioethics Center, 2012), 105.

[38] Ibid., 112–113.

[39] Aquinas, *Summa theologiae* I.76.1, I.76.8.

[40] Tadeusz Pacholczyk, "Principles of Medical Ethics" (class notes, Holy Apostles College and Seminary, October 8, 2012).

[41] Nicanor Pier Giorgio Austriaco, *Biomedicine and Beatitude: An Introduction to Catholic Bioethics* (Washington, DC: Catholic University of America Press, 2011), 174.

[42] Aquinas, *Summa theologiae* II-II.65.1.

[43] Francis de Sales, *Treatise on Divine Love*, trans. Henry Benedict Mackey (Rockford, IL: Tan Books, 1997), 481.

[44] Maureen L. Condic, "When Does Human Life Begin? The Scientific Evidence and Terminology Revisited," *University of St. Thomas Journal of Law and Public Policy* 8.1 (June 20, 2013): 48.

the embryonic human being simply requires the fulfillment of essential needs such as nourishment and shelter—needs universally recognized regardless of age. By impeding implantation and development, immunocontragestives act essentially as abortifacients.

Moreover, the immunological action of this contraceptive method relies on deception to attain its end. The immune system functions by identifying harmful pathogens like bacteria, parasites, and viruses as "non-self" entities, and then attacking and removing them from the body. Occasionally, "self" entities will also be targeted when illness or disease mutates their DNA, rendering them pathologic. Antifertility vaccines operate by deceiving the immune system, causing healthy and properly functioning entities within the human body to be identified as "non-self," thereby likening spermatozoon to a virus and—in the case of immunocontragestives—a new human being in its post-zygotic stage to a parasite.

Similar to other contraceptive methods of family planning, antifertility vaccines neutralize the procreative capacity of the sexual act. When intended, the use of such vaccines constitutes a deliberate violation of inseparability. This principle upholds the "inseparable connection ... between the two meanings of the conjugal act—the unitive and procreative meanings."[45] As this connection is intrinsic to the very act per se, it follows that any intentional sterility triggered via the employment of these vaccines is contrary to nature and its laws.

It must also be considered that every ethical assessment of human action involves the voluntary—that is to say, actions and omissions "over which man exercises personal control because he understands and wills these actions in relation to some end he has in view."[46] The application of antifertility vaccines raises serious concern regarding the potential abuse of informed consent. These vaccines are attractive because "developed and most of the developing nations have an infrastructure for mass immunization."[47] Associating antifertility vaccines with ethical immunization programs conflicts with the interests of providers and confuses potential recipients who may wish to receive licit vaccines to prevent disease but refuse to participate in schedules that elicit infertility. Conflict and confusion amplify significantly if a vaccine to protect against the acquisition of tetanus or diphtheria is tied to an antifertility agent. Informed consent, therefore, must remain truly informed (complete, understandable, and duly received) and consensual (free from moral dependence and physical constraints).[48]

Finally, the therapeutic potential of specific antifertility vaccines may justify such an intervention when a comparable or equally effective treatment against a proportionately grave threat is unavailable. The principle of double effect has applied

[45] US Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (Washington, DC: USCCB, 2009), 24. The Bishops referenced Paul VI, *Humanae vitae* (July 25, 1968), n.12.

[46] William Wallace, *The Elements of Philosophy: A Compendium for Philosophers and Theologians* (New York: Alba House, 1977), 150.

[47] Naz, "Contraceptive Vaccines: Success, Status, and Future Perspective," 2.

[48] Sgreccia, *Personalist Bioethics*, 602–603.

in cases that involve the use of medical interventions that treat a grave pathology while precipitating unintended infertility. This is known as therapeutic sterilization. Examples include the performance of a hysterectomy in order to remove malignant tumors or a double orchiectomy when aggressive testicular cancer is present. The action taken in either case is intended to preserve the patient's health and is therefore good. This preservation of health is not achieved through the rendering of infertility and is proportionate in comparison to its effect.[49] Marital acts following such an intervention remain legitimate provided the couple is "intimately and chastely united with one another" and that each sexual act "retain[s] its intrinsic relationship to the procreation of human life."[50]

The therapeutic application of an immunocontragestive, however, is far more complicated because of its abortifacient character. Moral culpability can be eliminated by observing temporary abstinence while the recipient is immunogenic in order to negate any potential contragestive action. If pregnancy already occurred prior to diagnosis, then serious deliberations must ensue to identify the consequences of delaying treatment until the child progresses to viability and what alternative methods of treatment are available that would benefit the health of the mother while sparing the life of the child in utero. It is imperative that throughout these deliberations the humanity of the preborn be recognized and given equal protection. If no alternatives are available and the need for intervention becomes dire, then the principle of double effect may again apply. An immunocontragestive employed solely to suppress a malignant hCG-secreting tumor is the proximate end directed toward the health and survival of the pregnant woman. The unintended consequence of this application is an assault on the hormone responsible for implantation and pregnancy maintenance. The effect of this consequence is not willed either as an end or as a means. A similar case of moral permissibility involves a woman requiring aggressive radiation therapy "to cure the cancer or protect her from dying of it even if she is pregnant and realizes that the unborn child will die as a result ... provided that no alternative therapies exist and those that do exist cannot be postponed until after the baby's safe delivery."[51] This tragic circumstance may result in an indirect abortion.

An Appeal for Morally Licit Vaccines

This essay has examined the current research in the field of reproductive immunology and concludes that the quest for an effective antifertility vaccine directed at human use remains elusive. Trends, however, suggest that certain targets—for example, human chorionic gonadotropin and sperm-surface antigens—continue to attract scientists either for their contraceptive or therapeutic potential. Moreover, the list of targets and conjugates detailed here is not exhaustive. Certainly the ingenuity of the human mind, the technological resources available for family planning research,

[49] Ibid., 200.

[50] Paul VI, *Humanae vitae*, n. 11.

[51] William E. May, *Catholic Bioethics and the Gift of Human Life*, 2nd ed. (Huntington, IN: Our Sunday Visitor, 2008), 169.

and the millions of dollars flowing from both governmental and nongovernmental agencies leaves considerable room for innovation.

Regardless of the target, eliciting an immune response to attack healthy and properly functioning "self" entities within the human body is unnatural. When this is intended by the recipient as a method of contraception, the principles of totality, physical integrity, and inseparability are violated. Similarly, the principles of inviolability of human life and non-maleficence are harmed when hCG is intentionally neutralized through a contragestive action. The principle of double effect can permit the use of certain antifertility vaccines when the formula prescribed by Aquinas is satisfied. Again, it must be affirmed that this principle can only be considered when there is no alternative to treat a proportionately grave threat to the mother. It cannot be used to justify campaigns that integrate a contraceptive or contragestive agent with a morally licit vaccine that inoculates against a specific disease. Certainly, providers can render a population immunogenic to those pathogens without eliciting infertility.

Furthermore, any integration of a contraceptive or contragestive agent with a morally licit vaccine would raise serious concern about the recipient's awareness of and consent to all foreseeable outcomes. This is not meant to be a provocative statement concerning the allegation in Kenya; rather, it is an appeal to manufacturers to fully disclose the composition of a given vaccine and to willingly agree to independent verification of both the primary and secondary effects of inoculation.

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