The issue of vaccines manufactured using cell lines which have their origin in aborted fetuses has received a fair amount of attention in the Catholic press, and the issue again became prominent with the publication of the Vatican letter on the topic in the summer of 2005. This paper will review the vaccination issue for the uninitiated, and examine the Vatican letter in some detail. Until now the discussion has been primarily limited to a handful of vaccines used in routine pediatric vaccination programs, and so the moral issues have been largely confined to parents of vaccination-age children and, perhaps, a few individuals working in the industry who might be thoughtful about the morality of the situation. I believe that the issue is poised to move out of this relatively circumscribed arena to affect virtually everyone, and quite soon. This is because several new vaccines using illicit human cell lines as culture media, including vaccines against influenza A and B and the avian flu, are well into the development phase, and in some cases are already entering clinical trials. These are vaccines which are, or will be, widely distributed. In addition, numerous other types of medical therapies, such as monoclonal antibody cancer therapies manufactured on these lines, are in development.

We will begin by discussing vaccines, and given the occasionally contentious nature of the topic of vaccination, I need to make perfectly and explicitly clear a couple of items. First, I absolutely acknowledge the usefulness, in general, of vaccination and of mass vaccination programs. After sanitation, mass vaccination has done more to improve the overall health and well-being of individuals and of populations than any other single measure, and it would be profoundly unwise to jettison something which

The views expressed in this article are those of the author and do not reflect official policy or positions of the U.S. Department of Defense. The author thanks Edward Furton for comments on an earlier draft.
has worked so well. Second, I do not contest in principle the authority of a government to require mass vaccinations under certain circumstances.\footnote{This is not to say that any vaccine that a government wants to initiate should not be viewed with scrutiny. There is much debate within the medical community concerning the usefulness of the H. flu (Haemophilus influenzae) vaccine and the varicella vaccine. But in principle it is not reasonable to contest the right of a government to require a vaccination program.} Third, I am not going to discuss vaccine safety. Vaccine safety is a profoundly important issue since, in a population-wide program, even rare events affect large numbers of people: a tiny fraction of a sizable number can also be substantial. Every effort should be made to monitor, ensure, and improve vaccine safety, and if questions regarding a vaccine or a component of a vaccine arise, they should be rigorously investigated. But I am not addressing vaccine safety here. In general, a vaccine is far safer than the disease it is attempting to prevent.\footnote{Again, with regard to specific vaccines such as varicella, this is debatable. But it is also a medical and public health question, not just a moral one.} To repeat: The first point of this paper is to review the moral status of parents who use vaccines manufactured with cell cultures derived from aborted fetuses. The second point is that, since the number of vaccines derived from the cell cultures of aborted fetuses is on the threshold of expanding exponentially, this issue will no longer be confined to a relatively small group of people agonizing over whether, in vaccinating their children or working in the industry, they are cooperating with evil. Rather, the issue will apply to vast segments of the population and, possibly, virtually everyone. The third point is that other therapies which could even eclipse the vaccines in number and importance are being developed using cell cultures of aborted fetuses. Central to all of these points is the issue of moral coercion of the conscience.\footnote{The phrase “moral coercion of the conscience” is not mine; it appears in the concluding paragraph of the Pontifical Academy for Life statement “Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Fetuses” (June 5, 2005), http://www.acadiaviita.org/template.jsp?sez=Documenti&paga=testo/vacc/vacc&lang=English; reprinted in this issue on pp. 541–549.} In other words, persons whose well-formed Catholic consciences indicate that using these vaccines could represent cooperation with evil are nevertheless required against their will to use the products. But first, a review of the facts.

The Pediatric Vaccination Question

In the United States, two vaccines in the routine pediatric immunization schedule utilize human diploid cell cultures in their manufacturing process. They are the vaccine against rubella (German measles), and the vaccine against varicella (chickenpox). The first vaccine, rubella, is usually given as a component of the combined measles/mumps/rubella vaccine M-M-R II (Merck), and the rubella vaccine component uses a live, attenuated rubella virus strain designated RA 27/3, grown in the human diploid cell line WI-38.\footnote{Merck and Co., M-M-R II package insert (1999), available at http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf. Links to the package inserts cited here are available online.} The rubella vaccine is also available as a single injection from the same
manufacturer under the trade name Meruvax II, which also uses the WI-38 cell line.\textsuperscript{5} The measles and mumps vaccine components in the combination M-M-R II vaccines are grown in chick embryo cultures, and therefore do not present a moral problem. The second major vaccine is a vaccine against varicella, Varivax (Merck). Introduced in 1995, it uses both the WI-38 and the MRC-5 human cell lines.\textsuperscript{6} A new combination vaccine, ProQuad (Merck), comprises M-M-R II and a stronger version of Varivax and was licensed by the FDA on September 6, 2005.\textsuperscript{7}

In addition to the rubella and varicella vaccines, there are other vaccines which, though not part of the pediatric series, are in routine use and do use “tainted” cell lines. The vaccines against hepatitis A, known as Havrix (GlaxoSmithKline Biologicals)\textsuperscript{8} and Vaqta (Merck),\textsuperscript{9} both utilize the MRC-5 human diploid fibroblast cell line to culture their hepatitis A viral strain; the viral particles are then inactivated and suspended for injection. While hepatitis A is not part of the routine pediatric series, it is required frequently for people who work in the food handling and other industries. Havrix is also offered in combination with the hepatitis B vaccine, Twinrix (GlaxoSmithKline).\textsuperscript{10} The hepatitis B vaccine component does not rely on viral culture; it uses recombinant DNA technology. For rabies, there are two vaccines licensed and marketed in the United States, RabAvert (Chiron), which uses chicken fibroblast cell lines for culture media,\textsuperscript{11} and Imovax Rabies (Aventis Pasteur), which uses the MRC-5 human cell line.\textsuperscript{12}

The moral problem is this: the WI-38 and MRC-5 human diploid cell lines used for viral culture, as well as the RA 27/3 rubella viral strain used in the rubella vaccine, are derived from fetuses aborted decades ago. Although a detailed and well-anno-

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tated history of the abortions related to the development of these lines is available in Debra L. Vinnedge’s “Aborted Fetal Cell Lines and the Catholic Family,”13 I will give a brief synopsis here.

In the early 1960s, researchers at the Wistar Institute in Philadelphia and the Merck Research Institute collaborated with physicians at the Karolinska Institute in Stockholm, Sweden, in an attempt to develop human cell lines for, among other things, vaccine viral culture media. The researchers were specifically looking for parents who had no medical problems either in themselves or (presumably) in their unborn child, but who wanted to abort the baby for “social reasons”; the social reason usually given was, “too many children.” The abortions took place in Sweden, as abortion at that time was illegal in the United States. It took the researchers thirty-seven attempts—representing twenty Swedish abortions—to develop a cell line that grew; this successful line was designated Wistar Institute 38: WI-38. In addition to a viable cell culture line, the researchers needed a strain of the rubella virus which had been demonstrated to cross the placenta and successfully infect an unborn child. A word on the reason for rubella immunization is necessary at this point.

The purpose of childhood rubella vaccination is not to protect the child, as German measles is a mild illness in children, and, as with chickenpox in children, natural infection confers lifelong immunity. The reason rubella is a public health issue is because if a pregnant mother who is unimmunized and, either by natural infection or vaccination, is exposed to a child with active rubella, she will get the illness, and it can be passed to her unborn child. “Congenital rubella syndrome” (CRS)—the constellation of defects associated with congenital German measles infection—can be mild, but it can also be devastatingly severe. CRS of some level of severity results from up to 85 percent of maternal infections that occur during the very early first trimester of pregnancy, but its incidence drops dramatically by the eighth week of gestation; if the mother is infected after the twentieth week, the incidence of CRS is zero.14 The reason for vaccinating children against rubella is not to protect the children themselves, but to prevent the transmission of the disease from an infected child to an unimmunized, pregnant mother and, from her, possibly, to her unborn child.

Since not all maternal rubella infections result in CRS, a rubella strain which had been demonstrated to cross the placenta and successfully infect an unborn child was necessary. During a rubella outbreak in Pennsylvania in 1964, pregnant mothers who had no immunity to rubella underwent abortions for fear of CRS. Organs from twenty-six of these aborted fetuses were cultured for rubella; only with the twenty-seventh aborted fetus was the virus successfully grown. This strain was then successfully cultured in WI-38, and designated RA 27/3, for rubella abortus, twenty-seventh fetus, third tissue extract. As noted above, it is the RA 27/3 rubella strain, grown in WI-38 human diploid cell culture, which is used in the Merck product.


Vinnedge estimates that no fewer than forty-seven elective abortions were involved in the development of the Meruvax vaccine: nineteen for the failed WI cell lines, one for the WI-38 line itself, plus the twenty-seven to culture the virus. A few years later, the Medical Research Council of England used similar techniques to develop the MRC-5 human diploid cell line from lung tissue of an aborted fetus.

**Levels of Cooperation**

In June 2005, the Pontifical Academy for Life, a division of the Congregation for the Doctrine of the Faith, released a statement titled “Moral Reflections on Vaccines Prepared from Cells Derived from Human Foetuses.”15 The statement was generated in response to a letter from the executive director of Children of God for Life, Mrs. Debra Vinnedge, and its purpose was “the liceity of vaccinating children with vaccines prepared using cell lines derived from aborted human foetuses.”16 Mrs. Vinnedge’s question “regarded in particular the right of parents of these children to oppose such a vaccination when made at school, mandated by law.”17 Although the document specifically addresses the pediatric vaccination question, its conclusion would certainly apply to others under “moral coercion” to use these vaccines, such as food industry workers for whom hepatitis A vaccination is a condition of employment.18

Before answering the question, the document expands on the theory that there are various forms of cooperation with evil. For those who, like myself, are theologically naive, the following is a review of the forms of cooperation with evil. The first fundamental distinction is between *formal* and *material* cooperation. In formal cooperation, one shares the *intent* of committing the evil. In other words, one agrees with the evil *act*. Whether it is the person who performed the abortion forty years ago, or a contemporary parent whose child is to be immunized with Varivax but who also agrees with the abortions, perhaps believing they were justified because “something good came out of them,” such formal cooperation is never licit. It is important to understand that this is true regardless of the closeness of the involvement: the parent who approves of the abortions shares, as much as the abortionist, in the illicit nature of the act.

In *material* cooperation, one shares the act, but *not the intent*. In other words, one is somehow associated with the act, but disagrees with the intent. Like formal cooperation, material cooperation has different levels of “closeness” (as illustrated briefly above). Material cooperation may be either *immediate* or *mediate*. In imme-

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17 Ibid.

mediate cooperation, one cooperates directly in the act. In mediate cooperation, one
does not participate directly, but performs some indirect function, such as providing
instruments or products, which supports the act. Cooperation can also be divided
into proximate (either spatially, temporally, or conceptually) or remote.

Immediate material cooperation is always proximate. It has to be proximate,
because one is directly participating in the act. When the evil is a grave matter, such
as participation in abortion, immediate material cooperation is always illicit.¹⁹
Thus, with regard to the abortions performed decades ago in development of the WI-
38 and RA 27/3 lines, one would conclude that the participation of the Wistar and
Merck researchers who collaborated with the Swedish abortionists at the Karolinska
Institute to procure the tissue behaved immorally because they were proximately
connected to the act, regardless of whether they personally agreed with the abortions
or not. Indeed, the document specifically addresses this type of cooperation, draw-
ing attention to those involved in “the preparation, distribution and marketing of
vaccines produced as a result of the use of biological material whose origin is con-
nected with cells coming from foetuses voluntarily aborted,” and concluding that
such activity is, “as a matter of principle, morally illicit.”²⁰

Mediate material cooperation may be proximate or remote. Since the nature
of the cooperation is not direct but indirect, it may be somewhat distant in terms of
time, space, or circumstance.

A further distinction is drawn between active (positive) cooperation with evil
and negative (passive) cooperation. The distinction here is between doing something
involved in the act versus sitting back and allowing the evil to happen when one has
a definite moral duty to impede it; this is summarized in the axiom “evil thrives when
good men do nothing.” Passive cooperation, like active cooperation, can be formal
or material, immediate or mediate, proximate or remote.

So how do these varying degrees of cooperation of evil apply to the vaccine
question? The Vatican paper identifies three categories of people: (1) those who make
the vaccines, (2) those who market and distribute them, and (3) those who use them.
We have already touched on the first two categories; the document condemns these
activities as morally illicit “as a matter of principle,” because “preparation, distribution,
and marketing ... could contribute in encouraging the performance of other voluntary
abortions, with the purpose of the production of such vaccines.”²¹ This is precisely
what is happening in society today, and my final section in this paper will be devoted
analyzing the third category. To finish with the document, however, it goes on to note
that within the production–distribution–marketing chain, there are varying levels of
responsibility. However, the document explains that the cooperation is “more intense”
on the part of those authorities, like medical councils and government agencies, that
recommend and implement the use of these vaccines.

²⁰ Ibid., 546.
²¹ Ibid.
The document then addresses the final category of people, those who use the vaccines. The parents who use the vaccines, as well as the physicians who administer them, assuming they are not in formal cooperation with the abortion (i.e., they do not agree with it), “carry out a form of very remote mediate material cooperation ... in the performance of the original act of abortion.” The same sentence also notes that those same parents are in mediate material cooperation regarding the marketing of cell lines coming from abortion, and immediate material cooperation regarding the marketing of vaccines coming from the cell lines derived from abortions. The document continues:

In this situation, the aspect of passive cooperation is that which stands out most. It is up to the faithful ... to oppose, even by making an objection of conscience, the ever more widespread attacks against life ... From this point of view, the use of vaccines whose production is connected with procured abortion constitutes at least a mediate remote passive material cooperation to the abortion, and an immediate passive material cooperation with regard to their marketing. Therefore, the paper continues, “fathers of families ... should oppose by all means ... the vaccines which do not yet have morally acceptable alternatives.”

Regarding those vaccines which have no alternatives (in the United States, this includes the rubella vaccine and the varicella vaccine), the paper notes that “it is right to abstain from using these vaccines if it can be done without causing children, and indirectly the population as a whole, to undergo significant risks to their health.” If there are significant risks, the paper continues, the vaccines may be used on a “temporary basis. The moral reason is that the duty to avoid passive material cooperation is not obligatory if there is grave inconvenience.”

In conclusion, the Vatican paper condemns the production, marketing, and distribution of the vaccines developed from aborted fetuses. It also condemns those public policy officials who implement their use. It supports those parents who make “an objection of conscience,” up to and including abstention from use (“it is right to abstain from using these vaccines”), assuming it can be done without “significant risk.” However, it does not condemn those parents who vaccinate, given the level of moral coercion which exists.

Before moving on to the next topic, I will make a couple of observations on a few key phrases in the document. “Therefore, ... fathers of families... should oppose by all means ... the vaccines which do not yet have morally acceptable alternatives.” Note is made here of the use of the word “yet.” In addition, I observe the use of the phrase “temporary basis,” in allowing that these vaccines may be used on a temporary basis if the risk of not using them is grave and there are no licit alternatives. Although not specifically stated, it seems to me that in choosing this sort of wording, the authors are writing under the assumptions that the use of human cell lines is receding and that these vaccines will soon be replaced by vaccines that are less “morally tainted.” As we shall see, nothing could be further from the truth.

22 Ibid., 547 (original emphasis).
23 Ibid. (original emphasis).
24 Ibid., 548 (original emphasis).
Human Technology
Manufacturing Platforms

In addition to the vaccines already discussed, several other vaccines dependent
on human diploid cell cultures are in development. The polio vaccine currently used in
the United States, IPOL (Sanofi Pasteur),\textsuperscript{25} comprises three strains of polio grown in
monkey kidney cultures. However, the same manufacturer has another polio vaccine,
Poliovax, which is cultured in the MRC-5 human diploid cell line. Although not yet
widely distributed in the United States, this vaccine has been licensed by the FDA.\textsuperscript{26}

Smallpox was declared eradicated from the planet in 1980, with the last re-
ported natural case occurring in Somalia in 1977. Routine smallpox vaccination was
discontinued in the United States in 1971, though it continued in the U.S. military
until 1990.\textsuperscript{27} However, subsequent to September 11, 2001, smallpox vaccination
was reintroduced in selected groups of the military, usually those who were in, or
scheduled to go to, the Middle East. The current smallpox vaccine, Dryvax (Wyeth),\textsuperscript{28}
was prepared from the traditional New York Board of Health \textit{vaccinia} strain pre-
pared in calf lymph and stored as a freeze-dried product. Although this freeze-dried
strain presents no moral problem, it is no longer manufactured in the United States,\textsuperscript{29}
and aggressive development of a second-generation smallpox vaccine is underway
using the MRC-5 cell line.\textsuperscript{30}

It is worth looking at this situation a little more closely. In October 2001, the
\textit{Washington Post} reported that a British company, Acambis, had been awarded a
contract from the Department of Health and Human Services (DHHS) to develop
fifty-four million doses of smallpox vaccine using the MRC-5 line. This information
was picked up by Children of God for Life as well as by the online news source
\textit{WorldNetDaily}, and these outfits conducted a poll of over thirty-three hundred per-
sons. Their findings were that 56 percent of those polled would refuse a smallpox
vaccine manufactured using cell lines derived from aborted fetuses. In addition, a
letter-writing campaign to the DHHS was organized, and as a result in December
2001 the DHHS modified the contract so that doses subsequent to the initial fifty-


\textsuperscript{27} S. Gorbach et al., \textit{Infectious Diseases} (Philadelphia: Lippincott, Williams &
Wilkins, 2004), 376.


\textsuperscript{29} K. Midthun, “Regulatory Requirements for the Historical and New Smallpox Vac-
FDA, G7+ Workshop in Langen, Germany, September 5–6, 2002, www.fda.gov/cber/smlpx/
smlpxreg090502km.pdf.

\textsuperscript{30} Ibid.
four million would be manufactured using the Vero monkey kidney line. At least two more human cell lines have been developed. The 293 cell line was developed from fetal kidney, and the PER.C6 line was developed in 1995 from embryonic retinal cultures obtained in 1985. The reasons for the abortion of the fetus which resulted in the 293 cell line are not clear, but that cell line was intended only for basic research. However, the medical details regarding the 1985 abortion are thoroughly documented. This is because, from the beginning, the intent was to develop this line as a basis for vaccine and pharmaceutical manufacturing, and since the researchers knew that the line would be submitted for FDA licensure, they needed scrupulous documentation.

The abortion was done in France on an unborn child of eighteen weeks gestational age, and the abortion was performed solely because “the woman wanted to get rid of the fetus.” There were no medical problems with the parents or with the unborn child. Indeed, the researchers wanted a healthy fetus; an unborn child with medical problems, or from parents with medical problems or with a family history of medical problems, would not be acceptable as a source of material for cell lines submitted for regulatory approval. The abortion was performed, the cells were procured from the retina, frozen, and ten years later thawed for the development of the PER.C6 line, a cell line developed “just for pharmaceutical manufacturing.” The researcher responsible for developing the PER.C6 cell line made this observation regarding the development of the line: “and then [there is] the pharmaceutical industry standard. I realize that this sounds a bit commercial, but PER.C6 [was] made for that particular purpose. Also, as far as I know, more than fifty different companies have taken license for PER.C6.” The company which developed and licensed the line is the Dutch biotechnology company Crucell.


34 Ibid., 94.

35 Ibid., 91.

36 Ibid., 94 (emphasis added).

37 Ibid., 95 (emphasis added). The researcher testifying this portion of the transcript is Dr. Alex van der Eb of the University of Leiden, The Netherlands. In the Disclosure section of the transcript, van der Eb also stated that he received consulting fees from Crucell (the company sponsoring the development of the PER C6 line) for “scientific advice” on human cell lines.
Crucell originated in 1993 as a company called IntroGene, which was formed with the intent of using stem cell technology to develop gene therapies. However, the company recognized that existing technologies were primarily for research and would not meet pharmaceutical industry standards, so in 1995, IntroGene entered into formal collaboration with Leiden University to develop the PER.C6 line, “initially intended for the production of virus-based products.” (“PER.C6” is a registered trademark of Crucell.) The PER.C6 cell line was introduced in 1997 for the commercial production of gene therapies, and in 1999 the line’s use was expanded. In 2000, IntroGene and a company called U-Bisys merged, forming Crucell. By 2001, the PER.C6 line was being reported in the literature as a “new manufacturing system for the production of influenza vaccines.” In 2002, the PER.C6 line was further expanded onto a commercial scale as one of the company’s two “broadly applicable human technology platforms” for developing pharmaceuticals. PER.C6, according to Crucell, will be used as a manufacturing system “on which a wide range of biopharmaceuticals can be developed and manufactured, such as vaccines, antibodies, therapeutic proteins and gene therapy products.” In addition to licensing the PER.C6 line to other vaccine manufacturers, Crucell purchased the Swiss vaccine company Berna Biotech in February 2006, making Crucell “the world’s leading independent vaccine company.” In August 2005, the company had a market capitalization of 735 million euros (this was prior to the Berna acquisition) and listed over forty licenses of the PER.C6 line. We will look briefly at some of the companies and products using this human technology manufacturing platform, but first, a few words about the flu.

“Seasonal flu” is the flu that people get typically in the winter months, usually caused by a strain of influenza A or influenza B. There is an influenza C virus as well, but the illness it causes is so mild that it is the least worrisome strain. Currently, there are two types of A (H1N1 and H3N2) and one type of B which circulate worldwide and cause seasonal flu.

“Pandemic flu” is an outbreak which spreads worldwide, and can be a public health disaster. Some type A strains occur in swine, horses, and other animals, but wild birds can carry any strain, and the avian strains H5 and H7 are particularly virulent. Pandemics are caused only by strains of influenza A, and some thirty pandemics have been recorded in the past several centuries (every ten to fifty years or so), with three
having occurred in the twentieth century: the 1918–1919 “Spanish flu,” the 1957–1958 “Asian flu,” and the 1968–1969 “Hong-Kong flu.” There have also been a couple of false alarms, like the “swine flu” scare in 1976. In the twentieth century, the 1918 flu was the most horrific, causing more deaths worldwide in a few months than World War I caused in four years. The Asian and Hong-Kong pandemics were far milder.

There is some evidence suggesting that the 1918–1919 pandemic occurred when an avian flu strain became capable of infecting humans, which brings us to the current avian flu concern. The avian influenza A strain H5N1 first made human contact in southern China in 1997, with an outbreak in Asian nations in 2003. Currently, about 177 persons have been infected worldwide with H5N1, with ninety-eight fatalities. Given the potential exposure of millions of people in southeast Asia to H5N1, the clinical disease in humans remains at this time a rather rare event. The concern among public health officials is that the genes of H5N1 could “mix”—reassort—with a human strain of influenza A, leading to increased infectivity and a pandemic. Please note that the potentiality of H5N1 to reassort and cause an influenza A pandemic is just that—a potential. It is, apparently, a very real potential, so it is prudent for governments to address the issue, but it is nevertheless a potential. At least one other avian flu strain—H7N1—seems to exhibit similar potential.

The vaccines for seasonal flu that are in current use were developed using viral strains grown in embryonated hen’s eggs. Each year the most likely candidate A strains as well as the B strain are selected, viruses are grown in the eggs, and fifteen micrograms of viral antigen are put in each dose. The process from strain selection to final product takes six to eight months, and because of the nature of hen’s eggs, it is time- and labor-intensive: each egg must be individually inoculated. Currently, there are multiple manufacturers for the seasonal flu vaccine.

Cell culture techniques are generally acknowledged to be superior to the use of hen’s eggs. It is especially important to note that cell cultures using Madin-Darby canine kidney (MDCK) cells or Vero cells (from African green monkey kidney) have been approved for human vaccine production and have the same benefits as those listed for PER.C6: greater production capability, less risk of transmission of avian flu virus (after all, H5N1 is a disease of poultry), and decreased labor requirements. In addition, there are numerous other strategies for developing a vaccine rapidly enough, and in sufficient quantities, to confront a pandemic. This is crucial to keep in mind as we move through the discussion which follows: PER.C6 or some other human cell line is not required to address the threat of an influenza pandemic with H5 or any other strain. There are other ways.


46 This synopsis on the flu was developed from various sources, including B. Kamps, C. Hoffmann, and W. Preiser, eds., Influenza Report 2006 (Flying Publisher, 2006), http://www.influenzareport.com/, an outstanding reference by an innovative online publisher.

47 Influenza Report 2006, chapter 6, “Vaccines.” See section titled “Vaccines and Technology and Development.” The author of the chapter, Stephen Korsman, does not list PER.C6 in his chapter, but only the animal cell lines.
The DHHS plans to phase out use of the egg-based vaccine and replace it with the cell-culture-based vaccine.\textsuperscript{48} It appears that this is planned for both the seasonal flu vaccine and a “pandemic flu vaccine stockpile.” The reasons are those noted previously: increased flexibility, less cumbersome manufacture, and higher antigenicity. The question is, Will the cell line be derived from animals or from aborted fetuses?

Sanofi Pasteur is the vaccine division of the French conglomerate Sanofi Aventis Group, based in Lyons, France. The U.S. corporate headquarters is in Swiftwater, Pennsylvania. In May 2004, the National Institute of Allergy and Infectious Disease (NIAID, a branch of the National Institutes of Health, which is under the auspices of the DHHS) awarded Sanofi a contract to develop eight thousand doses of investigational H5N1 vaccines. These were presumably egg-based doses. In November 2004, the DHHS announced that it had awarded Sanofi another $10 million to develop egg production facilities to ensure a continuous supply of eggs in the event of a pandemic or vaccine shortage.\textsuperscript{49} This represented the third agreement between DHHS and Sanofi to develop a pandemic influenza vaccine response; this third agreement had options for a total potential value, in addition to the $10 million, of $41 million.\textsuperscript{50}

So far, so good; this appears to be appropriate groundwork for egg-based H5N1 vaccines in the event of a pandemic. However, on April 1, 2005, the Sanofi Aventis Group announced that it had been awarded a $97 million contract by the DHHS “to speed production process for new cell culture influenza vaccines in the U.S.”\textsuperscript{51} The contract is to both develop the PER.C6 vaccine, \textit{and} design and develop a new U.S. \textit{PER.C6 cell culture manufacturing facility} in Swiftwater, PA. The same press release repeated the two main advantages of human cell culture over the usual conventional influenza viral culture medium of chicken eggs: (1) the cell culture technique decreases the start-up time for a new viral culture, from four weeks to three; and (2) it eliminates the need for all those eggs. In September 2005, Sanofi was awarded another $150 million to manufacture vaccine in bulk form at the Swiftwater location. Although unspecified in the press release, this is presumably the egg-based vaccine.\textsuperscript{52}

Finally, at the same time as the initial May 2004 contract, another vaccine manufacturer, Chiron (based in Emeryville, California, and Marburg, Germany) was also


\textsuperscript{50} Ibid.


awarded a contract by the DHHS for production and clinical testing of an H5N1 vaccine.\(^{53}\) This is an important fact: the Chiron investigational vaccine is based on the MDCK (Madin Darby canine kidney) cell line mentioned above. The Chiron vaccine is in U.S. phase I/II trials, and has completed a second phase III European study.\(^{54}\) So, like Sanofi, Chiron is rapidly developing a cell-culture-based vaccine. But Chiron is using an animal line, MDCK. Sanofi is using PER.C6. Sanofi Pasteur’s avian influenza (H5N1) vaccine is lagging behind the Chiron MDCK vaccine; Sanofi’s will enter clinical trials in Norway in the spring of 2006.\(^{55}\) Perhaps the extra boost from DHHS dollars will assist them.

Another biotechnology company, Vaxin, based in Birmingham, Alabama, announced a license agreement with Crucell on September 13, 2004, to use the PER.C6 cell line to develop vaccines against influenza, anthrax, respiratory syncytial virus (RSV), and other unspecified diseases.\(^{56}\) The influenza vaccine is especially interesting; unlike the Sanofi product discussed above, the Vaxin product is to be an *inhaled* flu vaccine developed on the PER.C6 line.\(^{57}\) The vaccine is already in phase I clinical trials, and full FDA approval is anticipated in 2009. To date, Vaxin has been awarded $10 million in federal funds to develop this product.\(^{58}\)

In addition to the influenza vaccines, the following is a short and far from complete list of companies developing new vaccines:

- The Aeras Global TB Vaccine Foundation of Bethesda, Maryland, contracted with Crucell for $2.9 million to develop a new tuberculosis vaccine using PER.C6, to replace the old BCG TB vaccine (not used in the United States).\(^{59}\)
- The PER.C6 cell line is being used in the development of Merck’s HIV-1 vaccine; this 2001 licensing agreement was actually the first for the cell line

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between Crucell and a major vaccine manufacturer. The research moved into phase I clinical trials in 2002, and it was recently announced that the candidate vaccines will move into “the next phase of clinical trials in the near future.”

- Crucell and the Walter Reed Army Institute of Research have signed an agreement to evaluate PER.C6 for the development of vaccines against Japanese encephalitis, dengue fever, and West Nile fever viruses.

At this point, a pause for a brief summary is in order. The following cell lines derived from aborted human fetuses are currently in use: WI-38, MRC-5, and PER.C6. The following vaccines use them: rubella (WI-38, as well as the viral strain originally grown out of RA 27/3), varicella (WI-38 and MRC-5), hepatitis A (MRC-5), rabies (MRC-5), and polio (MRC-5). Alternative vaccines for rabies and polio are currently available. Rubella once had alternatives; in fact, prior to the introduction of Merck’s WI-38 / RA 27/3-based vaccine, there were no fewer than three rubella vaccines licensed for use in the U.S. market. One was based on a duck embryo cell culture, one on a dog kidney culture, and one on a rabbit kidney culture. They were withdrawn from the U.S. market after the introduction of Meruvax, although at least two remain licensed by the FDA and could be “brought back on the market tomorrow.” Vaccines utilizing human cell cultures which are currently under development, or entering clinical trials, include those for smallpox (MRC-5), influenza A (PER.C6), influenza B (PER.C6), “avian flu” (PER.C6), tuberculosis (PER.C6), respiratory syncytial virus (PER.C6), HIV-1 (PER.C6), anthrax (PER.C6), and various encephalopathic viruses (PER.C6). This list is not inclusive, and pertains only to vaccines.

As is appropriate for a versatile manufacturing platform, in 2002 the PER.C6 line was “launched into commercial production of fully human monoclonal antibodies,” something totally divorced from vaccine production. This “launch” consisted of a formal collaboration between Crucell and the Dutch biotechnology company DSM Biologics, which develops biopharmaceutical products. The biopharmaceutical product market segment is currently worth more than $35 billion.
and is growing about 20 percent annually;\textsuperscript{67} in fifteen to twenty years it is projected to reach $200\,\text{billion}. As the director of DSM asserts, “PER.C6 has the potential to become the technology of choice for an attractive part of that market.”\textsuperscript{68}

\textit{Biopharmaceuticals} is roughly synonymous with another biotech buzzword, “monoclonal antibody (MAb) therapeutics.” Mabs are being increasingly used in cancer therapies, as they are directed at specific antigens found on the malignant cells. They attach to the antigens and activate compliment-mediated and cell-mediated cytotoxicity, resulting in death or arrest of the malignant cells.\textsuperscript{69} They are, in effect, “magic bullets” targeted at specific malignant cells, and thus have high specificity with minimal side effects. Currently, there are over a dozen monoclonal antibody therapies in clinical use, against certain forms of breast cancer, certain stomach cancers, certain leukemias, and certain lymphomas. I have observed the effects of a couple of these therapies; they are \textit{truly} remarkable. In addition, there is what has been described as a “bulging pipeline” of new MAbs against an even broader array of cancers and against chronic autoimmune inflammatory diseases with high morbidity rates, such as rheumatoid arthritis and ulcerative colitis. As far as I can tell, none of the existing MABs were developed using human cell lines, but Crucell as well as numerous other biotech companies are aggressively pursuing MAB development using human lines such as PER.C6.\textsuperscript{70} Interestingly, it is not just in anticancer therapies that MABs have potential uses; they may prove useful in infectious disease therapies as well. Research is underway looking at MAB therapies for severe acute respiratory syndrome (SARS, caused by a coronavirus)\textsuperscript{71} and rabies,\textsuperscript{72} among others. \textit{All} of the MAB therapies are amenable to development on human cell lines, although human


\textsuperscript{69}Z. Fishelson, “Obstacles to Cancer Immunotherapy: Expression of Membrane Complement Regulatory Proteins (mCRPs) in Tumors,” \textit{Molecular Immunology} 40.2–4 (September 2003): 109–123.


cell lines such as PER.C6 are not required. Animal lines such as Vero or MDCK work as well (and are generally the ones which are used in the research papers).

Finally, PER.C6 is being actively developed as a platform for various gene therapies. Like MAbs, this field will experience enormous growth in the very near future.

What Happens Now?

At the beginning of this paper, I stated that the question of the correct moral response to vaccines manufactured from cell lines derived from aborted fetuses was no longer confined mainly to the parents of small children and those involved in the industry. We have seen this is true: using just the pandemic flu and seasonal flu vaccines as examples, the question will quite soon face virtually everyone. Likewise, we have seen that the “vaccination question” really is not a question about just vaccines. The moral problems presented by the use of human cell lines derived from aborted fetuses are going to be attached to an ever-growing number of diverse therapeutic regimens: I believe that the day is not too far in the future when it will be easier to define what in medicine is not tainted by this evil, rather than what is, for this sort of corruption is going to invest itself in every aspect of the medical enterprise if we allow it. Nevertheless, the issue was raised in the context of pediatric vaccinations, and it is to pediatric vaccinations that we shall now return.

The Vatican document clarifies some issues regarding parental involvement in the evil of the original abortions, but it is, perhaps, a little too nuanced, and this has led to extensive and occasionally acrimonious disagreements among Catholic writers. The study appears to set a threshold for parental refusal of the vaccine at “no significant risk,” a threshold which is not easily defined. Regarding varicella, refusing the WI-38-based vaccine may indeed involve “no significant risk.” It is arguable that there should not even be a mass varicella vaccination campaign: the introduction in the United States of required mass immunization against varicella was controversial when Varivax was introduced in 1995, and remains so now. Indeed, outside the United States, only one nation—Germany—requires universal varicella vaccination as of 2005.73 Analysis by the Public Health Service for England and Wales concluded in 2003 that “routine infant varicella vaccination is unlikely to be cost effective and may produce an increase in overall morbidity.”74 Nevertheless, the U.S. Advisory Committee on Immunization Practices recommended universal pediatric immunization with Varivax in 1996, the year after the vaccine was introduced. These recommendations were expanded in 1999 to include vaccination requirement prior to a

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child’s entry into day care or school. Currently, the requirement for a second Varivax vaccination (essentially a booster shot) is under consideration due to the problem of waning immunity as a child matures to adulthood. Varicella, while innocuous in children, is a serious and potentially life-threatening illness in adults, and it is possible that we have traded relatively mild childhood morbidity for more serious future problems as the artificially immunized population ages.

The point is this: one can easily argue that abstaining from the varicella vaccine as an “objection of conscience” is the right thing to do, since physicians and government public health departments do not agree on whether it should be administered universally or not. Regarding rubella, the situation is more complicated. It could be that the vaccine is currently unnecessary in the United States, but this is only because of the currently low level of endemic rubella, which in turn is due to the high level of immunity, much of which has been supplied by the vaccine and its non-tainted predecessors. If immunization levels were to drop, the disease might reappear. In addition, even though rubella is at a low level in the United States, it is still widespread around the world; given the frequency of international travel, it is not unreasonable to posit that an unimmunized American child could, on an overseas trip, catch rubella and transmit it to an unimmunized mother, who would transmit it in turn to her unborn child. So the issue of whether or not to vaccinate for rubella is less clear regarding “significant risk.” Finally, when—the MRC-5-derived polio vaccine replaces the current polio vaccine, parents will have the choice of cooperating with evil (the document does not say the parent is not cooperating with evil, only that the level of cooperation is remote and excusable) or exposing their child to a very real and very devastating illness.

The document does enable us to evaluate the actions of those involved in the production and distribution of these products. We noted above that the document considers three categories of people: makers, marketers/distributors, and users, with parents and physicians in the last category. It is those in the first two categories we now examine. The document says that the activity of those involved in “the preparation,
distribution, and marketing of vaccines produced as a result of the use of biological material whose origin is connected with cells coming from foetuses voluntarily aborted” is “as a matter of principal, morally illicit.”77 If the activity of the original researchers at Merck, the Karolinska Institute, and the Wistar Institute back in the early 1960s was illicit—and I do not see how it could not have been—how much more so are the activities of the researchers at the University of Leiden who developed PER.C6; those at Crucell N.V. who develop and market the human technology manufacturing platform; and those at the fifty or more companies who license this “platform.” It would also be especially true of the DHHS, which is pouring hundreds of millions of dollars of money from U.S. taxpayers into, specifically, the PER.C6-based influenza vaccine program being developed by Crucell and Sanofi, even though licit alternatives are available—conventional egg-based vaccines and animal cell-culture vaccines.

The main difficulty with the Vatican document is that it does not address the larger reality that exists. As noted above, the document uses phrases such as “temporary basis” and “vaccines for which there are not yet acceptable alternatives,” suggesting that the authors believe this issue to be temporary, confined to a relatively small group of parents and likely to resolve itself. Though not explicitly stated, one gets the impression that the authors of the Vatican study believe that the pharmaceutical companies may not know the source of their cell cultures, or were unwitting accomplices in the development of these lines. And (this line of reasoning might continue) now that the manufacturers know the true source of these lines, they will distance themselves from the evil and pursue licit alternatives.

The reality is that pharmaceutical manufacturers and biotechnology companies are moving forward at a fast pace on the development and implementation of human technology manufacturing platforms, aided and abetted by taxpayers’ dollars, because such technologies are laden with profit, both current and prospective. The manufacturers know what they are doing, and they are not going to stop. We are at the dawn, not the sunset, of a new world utilizing human technology, a world in which this technology will intertwine with every aspect of medicine.

In developing a coherent response to this looming moral disaster, two points are worth considering. First, when considering the problem, we must realize that abortion is the murder of innocents, and deliberate killing of innocents—murder—is proscribed by the Church. If it is morally admissible in some circumstances (e.g., remote passive material cooperation under moral coercion) to use products whose origins lie in the murder of unborn children, then it should be morally admissible in the same circumstances to use products whose origins lie in questionable materials derived from human experimentation—for example, those obtained from murdered concentration camp victims. Perhaps the Church will teach that it is admissible to use these vaccines even if they were derived from immoral sources, and perhaps the Church will teach that it is not. But whatever the Church teaches, it should be the same in any situation.

The second factor to consider is this: The use of cell lines developed from aborted fetuses in manufacturing vaccines (or anything else) strikes me as no differ-

ent, conceptually, from using embryonic stem cells in other scientific research and development. The only difference is that the fetal cell lines are already being used, while the stem cell applications are still in preliminary studies. But in both cases you have unborn children being killed and disassembled for useful material, nothing more. The Pontifical Academy for Life document “Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells” states that use of stem cells, or cells differentiated from them, is illicit. Since the hypothetical “product” of the embryonic stem cell is the differentiated cell, it does not seem to be an unreasonable conclusion that the Church is heading in the direction of stating that the use of “products” derived from embryonic stem cells is immoral because their origin is immoral. I am unable to discern a significant conceptual distinction between products from embryonic stem cells and products from fetal cell lines.

As Charles Dickens says in *A Christmas Carol*, “these are scenes of things which might yet be.” As a nation, our government chose the evil fork in the road when it legalized contraception in 1965, and took the next immoral fork with the legalization of abortion in 1973. Initially, abortion “rights” were somewhat limited, but it took the fork labeled “unlimited abortions” in 1993. Today, the United States has the most liberal abortion laws in the world, with the possible exception of China. We live in a county where an abortion can take place for no reason whatsoever—and even in some cases late in term, when the baby is almost ready to be delivered. So why protest, when the abortions can produce something good and useful? We chose the evil road then; and now, like an ever-branching tree, the choices before us are multiplying faster, and are more bewildering: embryonic stem cell research, cloning, euthanasia, physician-assisted suicide, vaccines and cancer therapies whose origins are in aborted fetuses—the list grows longer. This paper has been about yet another pressing issue, just one of many: Do we allow ourselves to embark on the use of human technology manufacturing platforms, or do we not? They are not necessary; we can develop vaccines and monoclonal therapies without them. We can still choose the moral path, even at this late date. We can start to climb down from this tree. What, then, will we decide?

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78 Pontifical Academy for Life, “Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells” (August 25, 2000), http://www.academiavita.org/template.jsp?sez=Documenti&pag=testo/cellstam/cellulestaminali: “The third ethical problem can be formulated thus: Is it morally licit to use [embryonic stem] cells, and the differentiated cells obtained from them, which are supplied by other researchers or are commercially obtainable? The answer is negative.” The text does not make any distinction as to who is doing the “using,” researcher or clinician. Further, the title of the document makes it clear that the authors intend the conclusions to cover both research and therapeutic uses of stem cells.