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Jacob Heller  
*SUNY Stony Brook*

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# Rubella Vaccine and Medical Policymaking

# Fetal Rights and Women's Health

*Jacob Heller*

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*U.S. vaccine policies, to all appearances, are based on assumptions about cost effectiveness, safety, and public health needs. Analysis of the peer review health professions' discourse about rubella vaccine between 1941 and 1999 challenges this view. There were four justifications for the development of the vaccine: (1) cost-benefit projections about vaccine use versus anticipated birth defects; (2) the desire to prevent "fetal wastage" by vaccinating women; (3) a professional imperative to ensure healthy babies; and (4) a bias among vocal vaccine advocates against "unnecessary" abortion. The role of a fifth consideration, the "cultural provenance" of vaccines for American medicine, though not recognized by participants as part of the decision-making process presented in the literature, is hypothesized. Evidence published in 1991 substantiating the adverse effects of rubella vaccine for women highlights researchers' earlier assumptions about women's willingness to incur personal risk to prevent potential birth defects. The fetal rights movement (since 1980) establishes a language to help understand the social and scientific justifications for American rubella vaccine policies.*

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**R**ubella vaccine was the first and only vaccine for which no immediate medical benefits accrue to recipients. In all other vaccine programs, the cost-benefit equation includes improved individual immunity against disease for the recipient, as well as increased protection from disease for the larger community. These individual benefits form an important counterbalance to costs of vaccination, including its risk of adverse effects. Since smallpox vaccination was introduced around 1800, authorities have always stressed personal protection from disease as an incentive to individuals to submit to the vaccine. Because rubella — German measles — is extremely mild, often without recognizable symptoms, there is almost no disease to protect against. Rubella's interest to medicine and public health derives entirely from the fact that a pregnant woman who contracts the disease during her first trimester faces an increased likelihood that the fetus, if brought to term, will have birth defects. Rubella policies require vaccination of children and strongly recommend it for adult women for the benefit of a third party, the potential fetus.<sup>1</sup>

*Jacob Heller, a Ph.D. candidate in sociology, SUNY at Stony Brook, specializes in historical/comparative methods and the sociology of medicine, gender, and policy.*

The vaccine is not problem free. Its negative effects on women has received renewed attention in scientific literature. In 1991, in compliance with the National Childhood Vaccine Injury Act of 1986, the Institute of Medicine (IOM), an arm of the National Academy of Sciences, published an authoritative report on the adverse effects of pertussis — whooping cough — and rubella vaccines.<sup>2</sup> The report's findings largely exculpated pertussis vaccine, the site of much activism and contention, but concluded that the then-current rubella vaccine strain was causally implicated in both chronic and acute arthritis in women who had been vaccinated with it, especially as the recipients aged.<sup>3</sup> The authors of the report collaborated to summarize its results, which were published in widely read, high-status medical journals.<sup>4</sup> Despite these broadly publicized findings, however, rubella vaccination policy has not changed.

Mass vaccination always involves trade-offs in terms of costs, rights, and benefits between the individual and the community. The rationale behind mass vaccination — and of public health campaigns in general — upholds the rights of the larger community over those of the individual, demanding compliance for the benefit of the community. In mass vaccination programs, the otherwise sacrosanct rights of the individual to bodily integrity are superseded by the benefits believed to derive from high levels of conferred immunity in the population as a whole. By creating a pool of immune youngsters, mass vaccination policies would prevent rubella from establishing a foothold in the historically endemic group, children. As a result, rubella would become less transmissible to other parts of the population, particularly pregnant women. This is an application of the concept of herd immunity, in which only a limited, statistically determined proportion of a population has to possess individual immunity to a particular disease for the entire population to be free of it. The validity of this approach to rubella, a medical problem only when it occurs during a pregnant woman's first trimester, has been questioned.<sup>5</sup> Britain, South Africa, and Switzerland have enacted policies that limit rubella vaccination to specific subpopulations, usually teenage women likely to bear children, opting for a less comprehensive policy and more precise targeting than occurs in America.<sup>6</sup>

This analysis of the historical medical literature of rubella vaccine reveals American advocates' agenda to help women reduce the likelihood of rubella-associated birth defects and thereby protect women. Such protection, however, is one step removed from the health interests of women. It assumes the commonsense idea that women do not want to bear children with preventable birth defects, and that assumption, in turn, presupposes a particular social role and hierarchy of priorities in which women will bear children without the desire, willingness, or access to abort pregnancies. It decides what risks and steps they should take to avert or reduce the chance of delivering a rubella-affected child.

Since the late 1970s, as antiabortion groups began to invoke a discourse of fetal rights, it has become easier to recognize a nascent agenda in vaccine policy. The language of fetal rights treats fetuses as individual citizens deserving full constitutional protection, fitting many of the arguments used by researchers who wrote about the vaccine as a way to prevent fetal wastage. The intent of rubella policies is to protect fetuses against the effects of rubella infections, and researchers involved in the development of the vaccine clearly stated as much.<sup>7</sup> The juxtaposition of the health of a fetus and that of a pregnant woman in the discourse presaged an important aspect of the 1980s fetal rights dialogue.

Rubella policy, which essentially begins and ends with the vaccine, has historically taken for granted that women will incur any risks associated with the vaccine to obtain the deferred benefit of reducing birth defects. Because no vaccine is free of risk, the issue

of competing costs and benefits of women vaccinated against rubella and any fetuses they may or may not someday carry becomes important. Many women intend neither to become pregnant nor to bear children; for them it becomes difficult to parse out the promised protection. Immunized women of childbearing age do not contribute to herd immunity because they do not constitute a reservoir population for the disease; they protect from rubella-associated birth defects only the fetuses they themselves might carry and bring to term.

The historical record shows that, early on, researchers were aware of evidence about adverse effects of rubella vaccine for women, but nevertheless pursued a prevention strategy whose priorities were protecting fetuses and reducing fetal wastage. In 1969, as one physician summarized the medical research position at the largest rubella vaccine conference, "It was clear that rubella is a major medical and social problem, and the need for a safe and effective vaccine was obvious."<sup>8</sup> To this day rubella's public health cost is measured by its role in birth defects.

For medical researchers and vaccine advocates in the 1950s and 1960s, the connection between the social problem of rubella-affected fetuses and a vaccine as a medical solution may have appeared obvious. Social construction of problems theorists tell us that the claims which define a problem also structure the type of treatment used to contend with it.<sup>9</sup> In this case, the answer to pregnant women's problem of birth defects associated with rubella was to mandate mass vaccination of all children and subsequently to vaccinate as many adult women as possible. During these decades there was an important connection between viral infectious diseases and vaccines, and there is evidence of strong professional momentum for vaccine use in general. But the material connections between the social problem of children born with birth defects and the application of a vaccine to all children and later to adult women are more complex.

The physicians, public health officers, and medical researchers who developed and designed rubella vaccine did so to prevent birth defects by protecting fetuses from infection with rubella virus, not to improve the health of women. Physician-researcher attitudes toward women, abortion, and the role of physicians in managing communicable disease, specifically in the social and historical context of the vaccine's early development — American medicine in the 1950s and 1960s — had a heretofore unrecognized influence both on rubella research and on policy decisions. Indications of adverse effects for women appeared from the earliest tests of the vaccine, but were discounted in the overarching cost-benefit analysis that privileged what in today's language would be termed the rights of fetuses over the health concerns of women. Furthermore, the enthusiasm with which health professionals welcomed the vaccine into the modern armamentarium of disease prevention suggests factors beyond nominal efficacy or even an agenda of fetal rights.

I argue that the best explanation for the policy recommendations which emanate from the medical discourse involves a causal relationship to the zeitgeist of medicine at a particular historical moment and to the cultural provenance of vaccines in the late middle of the twentieth century. By cultural provenance I mean the legitimacy imputed to vaccines not by the scientific evidence, but by their meaning within the culture — their reputation, in a sense. This argument raises two questions or problems. First, how can the self-proclaimed objectivity of medical science be reconciled with evidence that a major public health protocol is informed heavily by nonmedical factors, namely, opposition to abortion? Second, with the new interpretation of evidence available in the Institute of Medicine report, how has the medical–public health establishment balanced the

rights of women not to risk arthritis against the socially desirable outcome of reducing birth defects? In the larger context of vaccines within society, this article addresses the question of what kind of cultural provenance vaccine policies carry and how they serve the needs of the medical and public health professions.<sup>10</sup>

Accepting the role of social values in determining implementation of rubella policy opens the door to a broader, more cultural interpretation of factors that motivated the enthusiasm for vaccines during this period and for rubella vaccine in particular. Vaccines were not, especially in the period from the dramatic testing of polio vaccine in the 1950s until the swine flu vaccine fiasco in the mid-1970s, just one among many medical or public health interventions. By the 1960s vaccines had once again become American medicine's most dramatic success story, outstripping even antibiotics, which had been found to be useless against recently discovered viruses. Vaccine history, beginning with Edward Jenner's smallpox vaccine at the turn of the eighteenth century,<sup>11</sup> followed by the dramatic use of Pasteur's rabies vaccine in the 1880s,<sup>12</sup> through the role of diphtheria vaccine in the establishment of legitimacy for bacteriological laboratories and statistical epidemiology in the early decades of the twentieth century,<sup>13</sup> is a story of a triumph and increasing status, especially as told by medical chroniclers.<sup>14</sup> Given the opportunity to defeat another disease with the vaccine weapon, it would be truly remarkable if American medicine and public health had not turned to vaccines, regardless of the indirect method of protecting fetuses and the adverse effects for the very population to be protected. That said, society relies on medical science not to follow fashions or trends but to be scientific about the development of preventives to protect public health. The medical and health professions' claim to their status depends largely, after all, on their science-based expertise.<sup>15</sup>

It is not difficult to conclude that preventing birth defects is a legitimate medical and social goal of medical policy. These data suggest, however, that an undeclared agenda, fraught with ethical and legal issues of individual rights, gender politics, and implicit — and sometimes explicit — opposition to unnecessary abortion influenced the cost-benefit estimate. Moreover, since the introduction of the vaccine, the liberalization of abortion laws and development of a fetal rights political movement have made it easier to recognize the issues included in the calculus for rubella vaccine's development and its mass immunization programs as neither inherently objective nor scientific. Finally, the compelling and authoritative evidence from the IOM report attests that rubella vaccine is not without serious adverse effects for women. This scientific development offers an opportunity to establish the place of objective scientific evidence in the adjustment of existing rubella vaccine policies since the IOM report.

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## **Data Sources and Method**

This essay looks at the history of rubella vaccine from 1941 to 1999 through the peer review medical and public health dialogue. To understand how seemingly nonmedical issues and priorities can animate medical policy decisions, it is necessary to examine the ways physicians, researchers, and public health advocates constructed the issues involved in the ongoing process of vaccine development and use. The presentation of argument, evidence, and policy recommendations materialized first and, most important, in the professional journals of health care and at major conferences. Researchers reported new evidence about rubella vaccine's adverse effects in medical journals, where any responses to the new evidence about them would appear. I use this public medical dis-

course to contextualize the vaccine's development and to understand the rationales and attitudes to justify the mass rubella immunization program that persists to this day. There is also discussion in lay publications about rubella and its vaccine that contests the orthodox interpretation of the facts. These nonmedical sources were, and continue to be, largely discounted by mainstream health professionals as unscientific, a product of what historian Richard Hofstadter described as the "paranoid style" in American politics.<sup>16</sup> They played little or no role in formulating or implementing rubella policies.

The literature leading to the development of vaccine provides evidence of the priorities, agenda, and purposes of medical researchers as they reported their findings, posed questions about prospective initiatives, and commented on the medical, social, and moral justifications for their research and that of others into rubella and the vaccine. Examination of the discourse following publication of the 1991 Institute of Medicine study implicating the vaccine in arthritis gauges the medical response to an example of the evidence the U.S. Supreme Court called an authorized, public, and official "statement that [represents] accepted majority views of specific medical tenets and practice."<sup>17</sup>

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## **The Rubella Vaccine Story**

### ***Early Rubella: To 1941***

Rubella, also known as German measles, is a mild, often subclinical childhood disease that poses few health problems to people who contract it.<sup>18</sup> Documented reports of rubella appeared as early as 1815, but it was not identified as a distinct and separate disease until more than fifty years later.<sup>19</sup> For the following seventy years, rubella was a disease entirely unimportant to any medical establishment, except to the extent that misdiagnosis would sometimes confuse it with measles or scarlet fever. In 1941 an Australian physician noticed a correlation that looked like a causal connection between rubella in women during early pregnancy and congenital cataracts in the children who were born to them.<sup>20</sup> Subsequent research confirmed the causal hypothesis about rubella and congenital defects, and the constellation of deformities associated with the disease in women during the first trimester of pregnancy was named Congenital Rubella Syndrome (CRS).<sup>21</sup> The most common birth defect is deafness, followed closely by blindness caused by cataracts.<sup>22</sup> As one vaccine researcher put it, rubella "was disparaged until 1941, when it received the imprimatur of greatness."<sup>23</sup> That is, its causative role in birth defects made rubella "interesting" to medical practitioners and researchers.

### ***The Prevaccine Period: 1941–1962***

After the 1941 discovery of the vaccine's role in birth defects, research attention increasingly focused on rubella; investigators made efforts to clarify its actual risks to the fetus and find the causative microbe, hoping to proceed swiftly to vaccine development. Consensus that rubella in pregnant women caused birth defects was neither immediate nor unanimous.<sup>24</sup> But the dramatic successes of polio vaccine in the early 1950s facilitated investigations that might lead to a vaccine, both conceptually and in terms of the allocation of resources, as vaccines became increasingly prominent in both medical and public consciousness.<sup>25, 26</sup> Though appearing in medical journals only sporadically, rubella was already emerging as a social problem beyond its toll on newborn children afflicted with CRS.

The inclination of some physicians to reduce the number of "unnecessary" rubella-associated abortions was among the most prominent arguments for development of a vaccine program. In 1952, a physician writing about abortion in the *New England Jour-*

*nal of Medicine* cited rubella as one of the top seven indicators for a therapeutic abortion, a medically sanctioned procedure that could circumvent stringent state laws restricting its use.<sup>27</sup> Because of rubella's mildness, especially before researchers identified the virus in 1962, it was difficult to verify cases. Physicians deciding whether rubella-related symptoms indicated therapeutic abortion usually had to rely on an indirect rubella diagnosis, which required them to listen to, believe, then interpret the after-the-fact testimony of women, not a strong point with many American doctors of this period.<sup>28</sup>

A physician reviewing the state of knowledge about rubella in 1952 asserted that "there is a definite danger in the assumption that the patient who has rubella in the early weeks of gestation should have the pregnancy terminated. The diagnosis of rubella is sufficiently vague to be easily abused."<sup>29</sup> Other physicians were outspoken in their opposition to medical complicity in therapeutic abortions and used such comments to support their argument against abortion and for a rubella vaccine: "Therapeutic abortion is . . . a direct violation of the fundamental ideals and traditions of medical practice."<sup>30</sup> In 1952 the editors of the *New England Journal of Medicine* voiced their concerns that incorrect estimates of the birth defect rate caused by rubella in pregnant women could pose social and psychological problems for them. The editors also expressed their agreement with the probably dominant view in the medical research community in the role of women in American society. They asserted that "the solution to the problem is simple — for young girls to 'get the disease and get it over with' before they undertake the responsibilities of marriage and motherhood."<sup>31</sup> Many published comments merely requested more and better information for making informed decisions about the risks of birth defects.<sup>32</sup> Studies in the 1950s attempting to ascertain CRS rates frequently cited abortion as a confounding factor in calculating precise results. Although these quotations might suggest unanimity on the issue, the same sources mention hospitals and clinics that "do not perform abortions."<sup>33</sup> They also cited a sizable proportion of institutions that regularly performed therapeutic abortions without protest.<sup>34</sup>

### ***Vaccine Development: 1962–1970***

Increased attention to rubella from established research laboratories bore fruit in 1962, when two independent groups, the Department of Tropical Public Health at Harvard's School of Public Health and the Walter Reed Army Institute of Research, published claims to having isolated rubella virus, and formal vaccine development began.<sup>35</sup> Not until the rubella epidemic in the spring of 1964, however, did the larger medical research community begin to pay attention to developing a vaccine; the epidemic had converted rubella from an esoteric physician's disease to national news.

The 1964 epidemic was the largest ever recorded in the United States. It was difficult to estimate its scope because the disease symptoms are so nonspecific, unalarmingly mild, and often entirely subclinical. The number of Congenital Rubella Syndrome-affected children born the following winter, however, was estimated at 20,000.<sup>36</sup> The epidemic became the precipitating event in the quest for the vaccine, especially as the practical cost of supporting so many disabled children made itself felt and the question became one of measurable cost comparisons. Epidemiologists reported that rubella epidemics occurred in six-year cycles, with an especially large epidemic to be anticipated approximately every two decades. This meant that the United States should expect another, probably smaller rubella epidemic in 1970.<sup>37</sup> There was little dissent in medical or public health circles from the notion that "the best means for preventing [the effects of the anticipated 1970–1971 rubella epidemic] is the proper application of an effective vaccine."<sup>38</sup>

By early 1969, three increasingly large international symposia on rubella vaccine had been held, and at least three candidate vaccines were before the U.S. Food and Drug Administration (FDA) for licensure. The published records of these symposia contain a rich record of attitudes glimpsed only rarely in the more formal presentation of research findings in professional journals. Introducing the 1969 rubella vaccine symposium in Bethesda, Maryland, the organizers set the tone for the meeting, saying that “it is only on rare occasions that people are so lucky as to find themselves assembled to mark the beginning of the end of a major disease.”<sup>39</sup> This is a clear statement of the crusading spirit that imbued vaccine proponents as they claimed responsibility for the reduction of infectious disease. For them, rubella was another vaccine campaign, much like polio, part of the war science fought against disease to protect innocent children.

Though plans for development and use of a vaccine were proceeding quickly, uncertainty about the CRS rate resulting from rubella infection during pregnancy persisted.<sup>40</sup> One problem with narrowing the incidence of CRS was, ironically, “the relatively low incidence of rubella in women of childbearing age” outside the 1964 epidemic.<sup>41</sup> Concerns beyond the epidemiology of the disease or the cost of medical care found expression as well. Researchers’ and vaccine advocates’ comments revealed some of the underlying motivations behind the push for a vaccine. The causal connections elided the important disease-specific differences between rubella and previous vaccination programs, and blurred distinctions about the identity of the intended objects of vaccination. “This tragic aspect [abortion, both spontaneous and clinical] of the rubella problem has been generally overlooked in published reports. It calls for more intensified efforts to improve laboratory methods for confirming the diagnosis of rubella and to develop effective measures for preventing infection.”<sup>42</sup>

Participants broadly recognized that CRS represented “by far the major problem of rubella as a disease” yet made consistent reference to the 1964 epidemic and “its toll of many thousand cases of fetal wastage.”<sup>43</sup> Its continuing theme highlights the concern about abortion, and the possibility of recurring epidemics made it especially important to some: “Fetal death and malformation of the newborn associated with a substantial increase in rubella cases is anticipated in the United States in 1970 or 1971.”<sup>44</sup> Such concerns were resolved into what can only be considered a consensus that “rubella is a mild childhood disease for which vaccine would not be considered if it were not for its effect on the fetus in utero.”<sup>45</sup> More plainly, “The aim in rubella is to prevent infection of the fetus.”<sup>46</sup> Another researcher-physician described the rubella-abortion connection as an “overwhelming personal tragedy . . . The extent of fetal wastage, and the expense accruing as a consequence of the recent rubella epidemic . . . is sufficient to indict rubella as a major medical and social problem.”<sup>47</sup> No other justification for rubella vaccination programs exists in the medical literature. Researchers never tried nor seriously considered any other method of contending with the disease.

In fact, the threads of the medical conversations about the vaccine show that some researchers considered abortion, legally available to women through the medical therapeutic loophole, an important social problem that rubella vaccine could eliminate.

Medicolegal and religious difficulties associated with therapeutic abortion and contraception are major facets of the rubella problem which can only be fully overcome by the use, early in life, of an efficient vaccine. Perhaps this will not receive universal acclaim as undoubtedly rubella has been the convenient scapegoat to terminate the embarrassment of many social *mésalliances*.<sup>48</sup>



Options besides vaccination, such as continuing therapeutic abortion, facilitated and informed by viral screening, were not discussed in this scenario. The overriding consensus was that a preventive vaccine would be safe and effective; with high compliance rates it could be a scientific solution to dealing effectively with the social problems of rubella.

The benefits of a vaccine that promises to reduce birth defects in women who wish to bear children are obvious. Medical discussions about vaccinating and protecting women elided this qualification, however, treating all women as eventual mothers and applying the rationale of mass vaccination with a twist. Indeed, the language shows a pattern of women as stand-ins for fetuses they might someday bear: "The public interest in preventing rubella is related to the pregnant woman. How to protect women of childbearing age is the main problem."<sup>49</sup> Women were considered the beneficiaries of the vaccine not just because they would become immune to the disease, but because they could deliver children without fearing birth defects. Physicians repeatedly discussed women as the "target group," the actual and final objects of rubella vaccine.<sup>50</sup> The transposition of women and fetuses as vaccine beneficiaries, however, is difficult to construe as incidental; the proponents of the vaccine considered women exclusively as fetus bearers.

### ***Adverse Effects of Rubella Vaccine***

Early on, researchers had established consensus about the relationship between rubella and joint pain.<sup>51</sup> Even as they touted benefits to the mother, physicians and researchers engaged in vaccine research dismissed reports of women's adverse reactions from their cost-benefit calculations, or simply the fact that *women* were being affected. As one group of researchers reported, "Direct protection of women [of childbearing age] by rubella immunization would be highly desirable. . . . Although the arthritogenic properties of currently available vaccines are unpleasant, they appear to be as transient as those associated with unattenuated (natural) infection."<sup>52</sup> The supposedly transient nature of the symptoms was less important than the group affected: one researcher commented gratefully, "The occurrence of transient rubella-like symptoms after vaccination is limited almost entirely to women."<sup>53</sup>

Conferring authority on this view, and contrary to theoretical reliance on herd immunity, the Public Health Services Advisory Committee on Immunization Practices suggested that, realistically, men should not be considered as vaccine recipients.<sup>54</sup> Another researcher explicated this logic, stating that "since the [rubella] vaccine offers virtually nothing to males, we can anticipate practical problems in inducing them to be vaccinated."<sup>55</sup> Unwillingness to consider men as targets for any rubella vaccine assumed that suffering would be limited to women whose children are born with birth defects, clearly revealing the gender stereotyping on which rubella policies were based.

Other concerns about the vaccine's adverse effects were noted, but ultimately dismissed. In the search for a vaccine that would immunize, it was important that the recipient did not become an infectious vector capable of spreading rubella to contacts, because such a situation, again, would "endanger pregnant women."<sup>56</sup> This concern centered on protecting women *qua* pregnant women. One group of researchers conducting such a study noted generally that "in considering the potential safety of a live rubella vaccine, perhaps our chief concern focuses on the fetus."<sup>57</sup> It was less important to ensure the safety and rights of the subjects involved in research.

In another paper describing a trial of the HPV-77 rubella vaccine candidate to determine its ability to transmit the disease from the vaccinated individual, conducted among "45 severely retarded children," one "5-year- old boy . . . died suddenly following an

episode of vomiting and aspiration 24 hours after receiving vaccine.” The authors concluded, however, that “there were no symptoms observed which could be attributed to the vaccine.”<sup>58</sup> Orphans and other institutionalized children often comprised the test populations for child vaccines during this period. One vaccine efficacy study conducted on institutionalized children at the later infamous Willowbrook State Hospital in Staten Island, New York — by none other than Dr. Saul Krugman of Willowbrook infamy — found it “impossible to evaluate the clinical results” because more than half the children in test and control groups had a “temperature exceeding 101° F.”<sup>59</sup> There is an important distinction between indifference to the safety of medical research subjects and indifference to women’s health in the advocacy of broad vaccination policy, but in this case they appear to coincide.

In the published record, Dr. Krugman, having cochaired the 1969 rubella vaccine symposium, emerges as a significant figure in the vaccine research. Krugman had established his impressive reputation as a pioneering vaccine researcher on his experiments in hepatitis, experiments that have since been roundly condemned as highly unethical — he intentionally infected healthy institutionalized children with hepatitis as part of his investigation into a preventive vaccine.<sup>60</sup> It is highly questionable whether the kinds of disregard for women’s health that appear in the medical records in the context of rubella vaccine are related to one individual. Nevertheless, the high praise and respect Krugman won for his research, including his doubtful methods, suggests that the dominant goal of vaccine development could easily override considerations of groups and individuals whose rights and health were not directly related to the goal of the project. The ends could justify the means.

By 1969, reports of adverse effects on women began to receive more direct attention, though not much action. At the 1969 Bethesda, Maryland, rubella vaccine conference, two of sixty-four papers explicitly dealt with women’s adverse effects from rubella vaccine; they bear extensive quotation because they reveal attitudes about the importance of the subject. The first was a study of women vaccinated just after having given birth and focused almost entirely on the effects on fetuses.

At the present time we do not know whether attenuated rubella virus strains completely lack teratogenic potential [the ability to cause birth defects], and it is important to avoid administering rubella vaccine during pregnancy. . . . Rubella vaccine could probably be administered to women receiving contraceptives. . . . In the first nine vaccinees arthralgia was not reported, but at that time we were unaware of that complication and no specific question was asked concerning arthralgia. In 23 mothers which seroconverted [as the result of vaccination with HPV-77] specific questions relating to stiffness, joint symptoms and pains were asked. One case of arthralgia was reported: pain appeared in the knees five days after vaccination, lasted three weeks without local inflammation, and disappeared without treatment. It is difficult to say if this case was vaccine-related . . . In comparison with observations of others, it seems that in this study with HPV-77 the incidence of arthralgia is low.<sup>61</sup>

The second article reported a study comparing the effects of two vaccine candidates “in adult women in an open field trial to compare vaccine effectiveness in stimulating antibody production and in relative frequencies of associated reactions.” Its authors reported their findings.

Arthritic symptoms involving knees, wrists, or fingers were the most frequent manifestation of reaction. Three women [out of 12] in each [vaccine] group had mild, transient arthritis which seldom lasted more than 24 hours and caused no appreciable disability. A

fourth woman in the group receiving HPV<sub>77</sub>DE<sub>5+IgG</sub> developed on day 13 a morbilliform rash and sore throat, followed by marked arthritic pain and swelling of the wrists and fingers. She was moderately disabled for nearly one week despite aspirin therapy. Three other women receiving HPV<sub>77</sub>DE<sub>5+IgG</sub> suffered minor episodes consisting of one or more of the following symptoms: headache, malaise, pharyngitis, or slight fever. . . . Both vaccine preparations were associated with arthritic manifestations in approximately one third of the volunteers, however, the Cendehill strain seemed to be more attenuated in this respect; arthritis was milder and of shorter duration.<sup>62</sup>

Other conference papers reported similar findings, but only incidentally. Together they established a consensus that all the vaccine strains had adverse effects on women, to varying degrees, which were considered acceptable.<sup>63</sup> In one case, researchers did not test the HPV-77 strain because “of our experience with the high incidence of joint symptoms.”<sup>64</sup> Cendehill, another strain, appeared to have fewer and less pronounced adverse effects than the other candidates.<sup>65</sup> One researcher summed up the attitude toward adverse reactions resulting from vaccines in general: “In the course of development and use of a number of vaccines, it was recognized that untoward reactions could occasionally occur, and the possibility was accepted.”<sup>66</sup>

It is important to bear in mind the particular historical point at which the rubella vaccine was developed. American medicine was enjoying what has since been recognized as its heyday, a continued period of ascendance. Soon afterward, outside intervention into medical decision making and administration would erode medical autonomy, cultural status, and the public’s confidence in medicine generally.<sup>67</sup> Advocates of rubella vaccine were quite explicit about their enthusiasm, as they enjoyed the benefits of the still-rising tide of public successes. Polio vaccine hero Albert Sabin commented in a roundtable discussion at the 1969 rubella symposium that although only about a fourth of the women who give birth every year “would be rubella-susceptible, but we could not identify these women unless we screened for antibody. Those without antibody are the ones who need vaccine, but as Dr. D. T. Karzon said, it might be simpler just to vaccinate them all.”<sup>68</sup> Screening for antibody was an important basis for earlier vaccine campaigns (for example, diphtheria, at a time when resources were comparatively less available),<sup>69</sup> but in rubella the idea was cavalierly discarded. Rather than vaccinate only those susceptible to rubella — those without natural immunity — American rubella policy has consistently advocated a blanket approach. Even within the vaccine paradigm, options existed that could have reduced risks to women, but they were rejected.

### ***Vaccine Use, the IOM Report, and Afterward: 1970–1999***

The FDA, in late 1969, began licensing rubella vaccine to head off the anticipated epidemic. Since then, physicians and public health organizations in the United States have consistently recommended rubella vaccine for all children, and it has been incorporated into the standard vaccine armamentarium of first world public health against birth defects.<sup>70</sup> It is slated for inclusion in the World Health Organization’s Expanded Programme on Immunization to bring vaccination to children in developing areas of the world.<sup>71</sup> With the herd immunity theory, mandatory mass rubella vaccination in the United States first focused on children.<sup>72</sup> The main reason for not vaccinating women directly seems to be that, historically, children, who have made the easiest targets for new public health initiatives, constitute a particularly natural target for vaccines.

Children were the first subjects for vaccination against smallpox; diphtheria, pertussis, and polio vaccines had been developed and used for these primarily childhood diseases. Children’s cultural value as innocents demands their protection, and their absence

of civil standing or formal legal rights outside the family makes imposing requirements on them comparatively easy. States have a simple gatekeeper to monitor vaccine compliance, requiring proof of vaccination — or religious or medical exemption — as a requirement for school attendance. Whether through application of the vaccine or for other reasons, the 1970–1971 epidemic did not occur. Predicted epidemics sometimes fail to appear, the swine flu vaccination program of the mid-1970s being the most famous failure.<sup>73</sup>

During the 1970s, limited criticism of rubella vaccine policy began to emerge in the medical literature. In 1970, one researcher remarked on the unorthodox strategy, “At the present, therefore, we are immunizing children in order to indirectly protect a third party, the fetus. This is a circuitous and unproven approach.”<sup>74</sup> A few years later, another commented, “Unlike the other live virus vaccines, which were designed to protect the vaccinated individual against the consequences of a serious infection, the intent of rubella vaccine administered to children was to prevent disease in third parties once removed — the as yet unborn human fetuses.” The same author recognized that “unlike poliovirus and yellow fever vaccines, which were essentially free of side effects, or measles vaccine, whose side effects were limited to transient fever, rubella-vaccine-induced arthralgia or even arthritis” were of a different order of magnitude.<sup>75</sup>

In a direct challenge to established policies, one immunologist questioned whether the absence of a 1970 epidemic could be traced directly to vaccine use, as well as the assumption that CRS could be prevented through establishing herd immunity among children.

Attempts to demonstrate “herd immunity” for rubella have been unconvincing. Also, some might argue that relatively little congenital rubella has been recognized since vaccination of children began in 1969. This reduction, however, can be accounted for by the infrequency of epidemics to congenital rubella syndrome, declining birth rates, and markedly increased availability of induced abortion.<sup>76</sup>

Though critical of the methods, these remarks did not challenge the continuing goal of rubella policy, protecting fetuses. Because they criticized childhood rubella vaccination, they served to advance policies to extend vaccination to women, who remain the target of immunization to protect fetuses.

Doctors increasingly reported “joint reactions” to the HPV-77 strain, and in 1973 the manufacturer voluntarily withdrew it from use because of its high rates of reactions in children.<sup>77</sup> But adverse reactions continued with the other strains, and lawsuits increasingly became a problem for vaccine manufacturers when individuals resorted to the courts to obtain compensation for damages. One outcome of the legal pursuit of monetary damages was passage by Congress of the 1986 National Childhood Vaccine Injury Act (NCVIA), which sought to please all parties. By limiting awards for damages, the NCVIA responded to complaints by pharmaceutical groups and vaccine manufacturers that liability costs were making vaccine production prohibitively expensive, an argument also employed to justify transferring vaccine research studies outside the legal jurisdiction of the United States.<sup>78</sup> The act’s no-fault provisions, making it unnecessary for affected individuals to establish culpability, addressed their needs. The NCVIA, however, has been cited as a weak compromise, especially because it has never been adequately funded.<sup>79</sup> Legislative recognition of problems with childhood vaccinations coincided with the increased interest in direct vaccination of adult women, the very group for whom adverse reactions to rubella virus had been a particular problem. The

NCVIA also commissioned a definitive scientific study of the adverse effects to help resolve the controversy, namely, the 1991 Institute of Medicine report, which substantiated the role of rubella vaccine in women's chronic and acute arthritis.

Since then there has been no change in rubella vaccination policy and almost complete silence on the subject in the medical literature. In one of the only direct responses to the content of the IOM study, praise was limited to the impartiality of the research. "The IOM Committee deliberately was composed of individuals who had not expressed polemic public views in these controversies and were neither blind advocates for the vaccines nor avid detractors of their use." The allusion to avid detractors is specious, because it is impossible to find anyone who continues to publish in mainstream medical or public health journals who seriously or consistently opposes vaccine policy. The term "avid detractors" is doubtless code for "lunatic" anti-vaccinationists, which lumps those with serious and legitimate concerns about rubella vaccine's safety together with fringe groups typically associated with opposition to vaccination. Respect for the objectivity of the research, however, did not translate into support for the aspects of the study that were critical of the vaccine. In the same article the author writes, "In my view, this relationship [between rubella vaccine and arthritis in women] is not established firmly and must undergo additional scrutiny before acceptance." This response stands in stark contrast to the medical community's eager acceptance of the IOM's finding "no evidence" or "insufficient evidence" for the adverse effects of pertussis vaccine.<sup>80</sup>

Since passage of the NCVIA, rubella vaccine recommendations in the United States have increasingly come to include adults. From 1985 to 1994, the American College of Physicians published three editions of its recommendations for adult vaccination; over the years, warnings about the adverse effects of the vaccine for women became less emphatic, apparently completely disregarding the IOM findings.<sup>81</sup> The authoritative report, like the 1986 act that commissioned it, provided validation for individuals' claims of adverse effects. Subsequent research appears to confirm the IOM findings, while other investigators found "no evidence of any increased risk of new onset chronic arthropathies or neurologic conditions in women" for the same rubella vaccine strain.<sup>82</sup>

Additional research teams confirmed increased adverse effects with an increase in age.<sup>83</sup> One article, entirely laudatory of vaccination, repeated the imprecation that "parents need to be reminded that their child is susceptible to these diseases, that these diseases are preventable by reasonably safe and effective immunizations and that their child needs a series of vaccines." The same article asserted the importance of complying with adult vaccine policies.<sup>84</sup> The underlying assumption that vaccines exist to protect the whole population from dangerous epidemic disease — therefore rubella vaccine performs the same function — continues to sustain our understanding of vaccines' value.

### ***Fetal Rights and Rubella***

The potential for conflict between the interests of an individual woman and the interests of those who would assign her the exclusive role of fetus-bearer are obvious; the most extreme case involves a woman's decision to abort a pregnancy. Without the details of abortion debates, suffice it to say that the procedure represents a conflict between the interests of a woman and her fetus, assuming, for the sake of argument, that the fetus is capable of a free-standing interest. In the early 1980s, the fetal rights movement, a new social and legal crusade, asserted that the status and civil rights of human fetuses were equivalent to or superseded the civil rights of pregnant women. Fetal rights activists insisted that a fetus is a legal "social actor" with full civil rights.<sup>85</sup> Over the same time, conceptual changes occurred as the separate entities, fetus and infant, became increas-

ingly blurred; the existence of an infant was chronologically extended back into the womb, which previously had housed only fetuses.<sup>86</sup>

While formal fetal rights legal theory is a relatively recent phenomenon, the medical profession has a long tradition of considering the fetus's rights in its therapeutic decisions about treatment, especially in the "utilitarian calculations" regarding pregnant women.<sup>87</sup> Physicians generally have taken upon themselves responsibility for fetal health, partly as a mainstream practice in support of many pregnant women's desires, but also as part of a compelling professional and cultural interest in maximizing the health and viability of prospective newborn babies. Rubella vaccination policies are consonant with this philosophy. No one advocates a policy that encourages more children's being born with birth defects.

Medical tradition assigns the responsibility to each pregnant woman, in consultation with an advising physician, to take positive steps to ensure the birth of a healthy child, assuming that a child is the socially and personally desirable outcome of each conception.<sup>88</sup> Obvious ethical and legal problems arise in cases when medical advice or intervention approaches coercion; in large measure, rubella vaccine, like all mass vaccination programs, falls into this category.<sup>89</sup> Children and women are compelled, in varying degrees, to accept the invasive preventive therapy of the vaccination for the exclusive purpose of preventing damage to unconceived fetuses, which will perhaps never be conceived. If rubella vaccine were entirely safe, without adverse reactions of any kind, this policy would indeed be difficult to question.

The argument for preventing rubella through mass vaccination has strong parallels to the one fetal rights advocates employ to press their case against abortion although, ironically, doctors have by and large defended abortion as a private medical decision.<sup>90</sup> Similar arguments have been used to attempt to restrict women's rights in the workplace, to prosecute "assaults" on fetuses by the women who carry them,<sup>91</sup> including legal cases brought against women for using drugs while pregnant,<sup>92</sup> and for refusing a caesarean section when rejecting it puts the viability of the fetus at risk.<sup>93</sup> In all these situations fetal rights advocates try to advance the notion of a compelling state, or more generally, community interest, to justify violation of a woman's bodily integrity. It assumes that women's health is subsidiary to the health of a potential fetus, and that in balancing interests, the fetus takes precedence.

The assertion of fetal protection through rubella vaccination, with its identification of the fetus as a full-fledged third party, is indicative of a willingness to consider fetuses deserving of medical and public health protections equal to that of women. Coming at a time when abortion was illegal, even though therapeutic administration was available, a virus causing fetal deformities could be expected to have a greater likelihood of resulting in the birth of a Congenital Rubella Syndrome-affected infant, a situation that changed with legalized abortion. The fetal rights position, in direct parallel to an important thread of the women's rights position, employs a liberal argument about individual rights.<sup>94</sup> Interestingly, the public health argument *for* vaccination opposes a radical interpretation of such rights.

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Mass vaccination is easily the single most prominent and popular American public health initiative of the twentieth century. Vaccines promise high efficacy, safety, and the rational application of scientific medical knowledge to protect the general population. Vaccination programs usually target children, and recommendations for their use rely

heavily on their reputation for an advantageous benefit/risk ratio.<sup>95</sup> The authors of the 1991 Institute of Medicine report testified, “Next to clean water, no single intervention has had so profound an effect on reducing mortality from childhood diseases as had the widespread introduction of vaccines.”<sup>96</sup> Together these ideas constitute a powerful cultural provenance for vaccines that encourages their broad use.

Controversies surrounding vaccination were exceedingly rare in the twentieth century.<sup>97</sup> When groups and individuals challenge vaccination policies, they often find themselves, and their claims, marginalized and discredited by virtue of challenging conventional wisdom.<sup>98</sup> Publicity about particular medical failures or mistakes occasionally results in a brief public exercise in muckraking and reform sentiment. Cases of a public perception of breach in the public trust, for example, the effects of thalidomide,<sup>99</sup> the Tuskegee syphilis study,<sup>100</sup> the excesses at Willow-brook,<sup>101</sup> or even the swine flu vaccine fiasco of the mid-1970s,<sup>102</sup> have worked this way. They have generally not effected fundamental changes at the moment of public revelation, but rather contributed slowly to the erosion of public confidence in medical decision making, ethics, or policies.

If, as has long been argued quite convincingly, “rational” policy is the exception rather than the rule, what factors can account for the origination and persistence of rubella vaccine policy?<sup>103</sup> The orthodox story reported in traditional and internal medical history recounts a community of researchers trying to translate scientific findings into medical policies.<sup>104</sup> In the case of rubella vaccine, physicians did not use medical criteria only, or perhaps primarily, when evaluating costs and benefits associated with their research. Moral and social concerns infused and confounded both medical research and policy recommendations.

The evidence presented here suggests that cultural and professional prejudices permeated the rubella vaccine research process and constrained the uses of scientific knowledge that militated against vaccine use. The direction of the research was influenced by and rooted in social rather than medical or scientific choices about women, fetuses, and the presumed role of vaccines in public health initiatives. The overmastering impetus for the creation and use of the vaccine was the prevention of unnecessary birth defects, but a strong nonmedical component, centered on opposition to abortion, rendered invisible the real ethical dilemma of third-party vaccination.

Since the 1950s, important social developments have transformed the context of rubella as a public health hazard. I argue, among other things, that the social context was important in the formulation of rubella policies. Once in place, however, those policies have only expanded the groups being vaccinated. Individual legal successes in claiming adverse effects of rubella vaccine led to enactment of the 1986 National Childhood Vaccine Injury Act. This is only the most concrete example of a nonmedical factor intruding on medical rubella policy: tort litigation — financial duress — compelled vaccine manufacturers to admit that their product was less safe when scientific evidence of safety problems did not. Rubella vaccination policies have been exceedingly resilient: vaccine administration remains a requirement for children, and since the mid-1980s, recommendations from the medical and public health community have increasingly included adult women.

Changes in the social context have important ramifications for understanding the status of the vaccine. The changing role of women, a liberalized sexual culture, and the availability of safe and legal birth control methods provide a comparative context for understanding the motivations behind rubella policies. Most of all, changes in the legal

status of abortion before and after the 1973 *Roe v. Wade*, legalizing abortion on demand, is important for unpacking nonmedical considerations around rubella policies.

Aborted fetuses are generally not screened for rubella traces, so the dramatic increases in legal abortion since *Roe v. Wade* introduced additional uncertainty into epidemiological measures of the incidence of Congenital Rubella Syndrome: by 1973 defective fetuses could be aborted legally and relatively easily. In technical terms, determining reliable CRS rates had been a problem before the introduction of vaccine — or even legalized abortion, owing to the frequency of *therapeutic* abortion<sup>105</sup> — and the difficulties in estimating the rate of rubella only increased after 1973. Of course, concerns about excessive or unnecessary abortions continue to be an important and controversial topic of discussion in medical circles, as elsewhere. But before 1973, women who claimed to have had rubella or rubella-like symptoms during the first trimester could obtain therapeutic abortions, often the only legal option for U.S. women. This created an ethical quandary for physicians, which effective application of a vaccine would eliminate.

There is no reason to believe that *Roe v. Wade* altered any individual physician's or researcher's personal beliefs about abortion. It did, however, free the physicians and researchers from having to make policy decisions about how, or whether, rubella-associated abortions should be discouraged, at least in the context of rubella. The 1973 legalization eliminated the need for any woman to claim rubella as a pretext for therapeutic abortion; that particular ethical dilemma evaporated for physicians. They were left to wrestle only with their individual ethics on whether to perform abortions. (Some hospitals do not permit abortions to be performed on their premises.) *Roe v. Wade* removed unnecessary abortion from the rubella equation. Retrospectively, it also clarified the issues involved in the formulation of rubella vaccine policy.

Evidence presented in the 1991 IOM study — clearly a much smaller event than any revelations associated with thalidomide or comparable medical and public health tribulations — received little or no comment in the health literature, and effected no changes in rubella vaccine policies. On the contrary, since 1991 there is evidence of changes broadening rubella vaccination recommendations for adult women, regardless of possible consequences. The data from the prevaccine period, richer in both variety and content, establishes the reluctance to recognize the risks of rubella vaccine to women as an integral part of the history of the vaccine.

Physicians and medical policymakers continue to claim a rational, objective, utilitarian calculus as their guide in ranking threats to the public health.<sup>106</sup> They invoke arguments about cost-risk ratios and the common good of society, especially when their recommendations for public health require individuals to surrender some part of an inviolable personal or individual right.<sup>107</sup> With rubella vaccine, it is difficult to give full credence to claims of objectivity and interest in the public welfare if the records in the literature and the IOM report's conclusions are to be believed. The possibility of chronic arthritis in women, especially as they age, was not considered a public health threat capable of competing with CRS.

Because physicians and medical researchers are not insulated from society but are part of it, they used the social values associated with opposition to “unnecessary” abortion as a motivator for research and policies that made rubella vaccination part of the standard canon of public health. The legal and social acceptance of abortion apparent by the 1970s could logically have been expected to affect the research agenda and policies advocated by the medical community, especially in cases like rubella vaccine, which involve fetal protection. This has not been the case. More fundamentally, the IOM's



authoritative report stated that a causal connection between rubella vaccine and arthritis in women, according to the medical model of research agenda and policies, should have generated a more coherent and thoroughgoing reevaluation of rubella research and policies. Even discussion of such changes had not, by early 1999, materialized in the peer review medical and public health discourse. Sensitivity to the social and medicolegal issues raised by unnecessary abortions resulting from rubella competes with authoritative medical evidence of serious adverse effects of vaccine. More important, the cultural provenance of vaccines, including their status as problem-free preventives that protect all of us, helps keep rubella vaccine policies in place despite contravening evidence about their safety or the historical record about whom the vaccine protects. Rubella vaccine is an early and important example of the formal implementation of a policy to protect fetuses that predates the recognized beginning of the fetal rights movement by at least three decades. The history of medical protection of the fetus stretches as far back as the Hippocratic prohibition on abortions, but it no longer constitutes a formal cornerstone of medical philosophy. Since *Roe v. Wade*, physicians have jealously guarded their right to perform abortions as a professional prerogative.

Whether vaccines are truly responsible for reducing epidemic infectious diseases remains the subject of some controversy.<sup>108</sup> Their cultural importance, however, is not in doubt: vaccines retain their cultural value, and it remains important to understand the kinds of issues and factors that have informed the vaccine policymaking process and its outcomes. Physicians base their claims to whatever special status they enjoy, at least partly, on their station as experts — on their scientific, objective, and entirely medical qualities.<sup>109</sup> As a group and as a profession they are nominally apolitical and do not enter into nonmedical arenas except as experts, advisers, and to advocate for their own professional interests.

This research suggests that medical attitudes toward rubella vaccine are not satisfactorily explained by the “internalist” model, in which physicians are driven purely by medical-scientific concerns about the epidemiology of disease.<sup>110</sup> Concerns about unnecessary abortion pervaded the peer review research literature on rubella vaccine, and theories about producing herd immunity cavalierly eliminated men from any prospective policies. At the same time, authoritative medical evidence, for example, the IOM report, remains largely ignored. *Roe v. Wade*, which legalized abortion even after the first trimester, removed formal structures opposed to rubella-based therapeutic abortion, though medical priorities about delivering healthy babies persisted. These findings suggest that a more promising hypothesis to explain the continued expansion of rubella vaccine usage includes the structural and professional needs of physicians. A cultural, rather than scientific, reliance on the vaccine model of preventive public health administration better explains the consistent support for rubella vaccine despite changes in both the social and medical contexts.

Such a hypothesis necessarily includes aspects of the rational and scientific approach to medical policy recommendations. At the same time, it is sensitive to the historical meaning of vaccines for both physicians and public health agencies. Vaccines are not, by any stretch, like other medical or public health interventions. Their success is broadly esteemed, and their use goes largely unchallenged, except by a few religious groups and small but organized social movements whose cultural location is at the margins of society’s legitimacy.❧

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