



More than Skin Deep? Concepts of Racial and Ethnic Difference in the New Genetics

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The recent dramatic progress in sequencing the human genome has kindled renewed interest in understanding how racial and ethnic groups may differ biologically. Many researchers are currently studying the distribution of genetic variations among diverse population groups, with particular interest in explaining racial/ethnic health disparities. However, it is unclear whether sufficient care is being exercised in the ways that race/ethnicity is being conceptualized and operationalized in this line of research, and what the scientific implications of this lack of care might be for the legitimacy of race-based genetic findings. In examining how a group of genetic scientists talk about using race and ethnicity in their work, we will see that the racial/ethnic variables commonly used in genetic research lack adequate definitions and classification procedures, undermining any conclusions that might be drawn about racial genetic differences.

Resurrection of Biological Race?

The idea that the human species can be reasonably divided into biologically distinct races has long been rejected by anthropologists and biologists, who maintain that race is a social and historical fact, rather than a biological reality, noting that there is more variation within racial groups than between them. They agree that racial identity has important implications for the health of racially labeled groups, but those implications reflect long-term social rather than biological differences.¹

Still, the idea that racial groups differ biologically has an inherent logical appeal in our culture, and indeed, racial/ethnic variables are currently being widely used in an impressive variety of human genetics endeavors, such as studies modeling human evolutionary history and migration patterns; research on differential disease distribution; efforts to tailor treatment to specific racial/ethnic groups; and services to help individuals identify the racial origins of their progenitors.²

When studies such as these report genetic differences between so-called racial groups, it may seem to that we are amassing increasing evidence for the biological reality of racial categories. However, on closer inspection, we will see that the racial categories studies such as these draw on are highly problematic, decidedly undermining the credibility of any such claims. There are many challenges that have already been raised about the “science” of such generalizations, ranging from over-interpretation of very small and inconsistent results, to the failure of genetic markers to cluster along racial lines. In this paper, we focus on a very basic question: we examine the scientific adequacy of the racial/ethnic labels themselves, which are most commonly used in health research. We will argue that, while the familiar terminology such as “African American” or “Asian,” may appear to be a matter-of-fact way of classifying objective identities, in fact these are highly amorphous labels, promoting an illusion of coherence between diverse studies, where coherence cannot be presumed to exist.

Racial/Ethnic Classifications Used by Geneticists

With support from the National Human Genome Research Institute's (NHGRI) Ethical, Legal and Social Implications (ELSI) Research Program, we conducted open-ended interviews with a group of 30 human genetic researchers regarding their concepts and practices in using race/ethnicity as a variable in their research. This was a purposive, snowball sample of scientists at 15 universities and health research institutions, in 8 U.S. states and Canada. They were all Principle Investigators with PhD and/or MD training in a cross-section of specializations including molecular biology, biochemistry, epidemiology, bio-statistics, human genetics, physical anthropology.³

All of those we interviewed routinely use racial/ethnic categories in their research, and most used them as central variables in their studies of genetic variation. When asked which racial/ethnic categories they use, these researchers most commonly listed the familiar racial/ethnic labels of the U.S. Census (African American, Asian, etc.) This is not surprising, given how ubiquitous these common labels have become in health research. Their use has been promoted to a large degree by efforts to assure that health research be inclusive of all citizens. U.S. federal law has required, since 1993, that federally funded research include women and minorities. In enforcing this requirement, National Institutes of Health (NIH) has been using the racial/ethnic categories of the Office of Management and Budget's (OMB) in their reporting requirements.

Most of the researchers we interviewed noted that these labels are less than ideal, as they are vague and ambiguous. But they nearly unanimously defended their use, saying that they are straightforward and easily assigned categories, and that they have obvious utility in capturing some important variation between population groups. But is this really a reasonable and parsimonious approach? First, let's consider the categories themselves.

According to Bowker and Star (1999), there are three basic features a sound classification system should have: 1) consistent and unique principles of classification; 2) categories which are mutually exclusive, and 3) capacity to absorb all cases. Do these racial/ethnic categories meet these criteria? Table 1 presents the labels these geneticists most often said they use, and suggests the types of classifications they seem to reflect.⁴

Do these racial/ethnic categories exhibit properties necessary for a classification system? Clearly, they are not consistent, mutually exclusive, or complete. Instead, they represent a bewildering array of unrelated characteristics, ranging from appearance to presumed ancestral origins, to language and location. Although perhaps appearing to be obvious categories to people who share our cultural and social notions of racial/ethnic groups, they do not constitute a solid classificatory scheme. They intermix a variety of features in an arbitrary and haphazard way. As a result, any given individual may reasonably be assigned one or another label, depending on which characteristics are prioritized. Thus, the criteria for applying the labels are important to consider in evaluating their adequacy.

Methods for Classifying Individuals

A rather distressing realization in analyzing these interviews is that, despite the arbitrary and overlapping nature of the racial/ethnic classifications themselves, there appear to be no established procedures at all for classifying individual cases. The researchers we spoke with described 45 different projects in their interviews. In the vast majority of these, they said they used "self-identification" by the subjects themselves as their primary way of classifying samples. At first glance, this may seem a reasonable approach, treating the individual as the best authority on her/his own identity. However, this method is deeply problematic.

Merely asking a subject to choose a label from the standard OMB list resolves none of the problems inherent to the labels themselves. Instead, this compounds those problems by allowing the idiosyncratic and unexamined criteria each individual may choose to apply to determine which label is to be used. In a handful of projects the researchers said they used an open-ended approach, recording whatever labels the subjects volunteered. However, at some point before reporting the data, those responses will be reclassified into the standard classifications. None of the researchers could say exactly how that would be done.

Imprecision and the Illusion of Consistency

Thus we find ourselves at a rather frustrating juncture. The researchers agree that these are inadequate categories, and they describe no concrete classification methods or procedures. However, they reason that while imperfect, the labels provide a quick and easy shortcut to get at what's really important: ancestry. As one population geneticist put it: "When I refer to ancestry, I mean the genetic contributions from different continents that you can estimate with genetic markers."

But, does focusing on "ancestry" resolve any of the problems we've reviewed thus far? Consider that the terms they choose in trying to clarify what they meant by "ancestral groups" were phrases like "African Ancestry" or "Hispanic Ancestry," which merely restate the already problematic racial/ethnic labels, and thereby replicating the same problems.

Put in these terms, this reasoning seems impressively tautological: common racial/ethnic labels are useful, although they are not very well defined, because they are a shortcut to what's really of interest, which is ancestral genetics. "Hispanic" or "African American" are poor labels, but useful because they approximate "Hispanic" or "African" ancestry.

But how could researchers in such an otherwise rigorous field be so tolerant, even embracing of variables with so little precision? We argue that in part, it is precisely this imprecision that sustains itself. The wide use of this vague and unsystematic terminology results in a semantic illusion of consistency between very different types of research. For example, those we interviewed were working on a wide assortment of types of genetic studies, ranging from DNA sequencing, population modeling, to linkage studies. Their target populations were equally varied, depending on the goals of their project: some chosen because of their geographic isolation, others for their disease characteristics, and others for their mere availability. However, when all are labeled with the same simplistic set of terms, it may seem that there is a growing body of data about specific racial populations, when in fact there is no reason at all to presume they belong to a "group" of any kind, beyond their being subject to having the same label affixed to them. In other words, the only equivalence that can be presumed between these groups is that they are subject to equivalent terminology.

These problems may seem academic and esoteric, but their effect is current and real. Consider, for example, that 60 Mormons living in Utah are labeled "European" in one major data set, while 25 people from a small village in central China are taken to represent "Asians" in another, and a handful of people in a particular zip code in Texas represent Hispanic Americans. We contend that the high tolerance for these scientifically questionable practices is rooted in a set of shared notion about human origins that are based more on myth than reality. These include the erroneous beliefs that: 1) Racial/Ethnic groups are essentially endogamous, 2) Humans rarely moved between continents in the past, 3) Gene flow between groups is rare and recent, 4) Racial/Ethnic Groups are discreet and homogenous, and 5) Boundaries between groups are fairly well delineated.

We are continuing our analysis of these interviews, and a critical analysis of the emerging literature on race and genetics, and will continue to explore how folk notions of human history

and difference permeate the otherwise rigorous field of human genetics. We are in the process of developing a critique considering how research ethics and the idea of scientific integrity might be expanded to address the use of race as a variable in human genetics. See Hunt & Megyesi, 2007a and 2007b for further discussion of our emerging findings.

Table 1 Racial/Ethnic Classification Terms Most Commonly Used by 30 Genetic Researchers and Types of Classification they Appear to Represent.⁵	
Classification Term Used	Type of Classification
Caucasian	Skin Color or Geographic Origin
White	Skin Color
Non-Hispanic white	Language & Skin Color
Jewish/Ashkenazi Jews	Religion & Geographic Origin
Asian	Continental Origin
Asian American	Continental Ancestral Origin & Geographic Region
African American	Continental Ancestral Origin & Geographic Region
West African	Geographic Region
Afro-Carib	Continental Ancestral Origin & Geographic Region
Hispanic/Latino	Language
Mexican	Country
Mexican American	Country of Ancestral Origin & Geographic Region
Native American	Ancestral Group Membership

Notes

1. American Anthropological Association, 1997; Goodman, 2000; Lewontin, 1972.
2. See for example: Burchard et al., 2003; Cohn, 2006; International HapMap Consortium, 2003; Risch et al., 2002; Stern, 2002.
3. For more detail on the study design, see Hunt & Megyesi, 2007b.
4. Table 1 is taken from Hunt & Megyesi, 2007b.
5. Terms were included in Table 1 if they were mentioned by at least 4 different researchers in interviews when describing their own research projects. The labels used for “Types of Classification” are meant to be descriptive, and are based on a consensus amongst our project team, in consultation with the Random House Unabridged English Dictionary, 2006.

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The State of Gardasil: The Political Implications of the HPV Vaccine

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More than 3,500 women die from cervical cancer every year in the United States, and new studies now identify the human papillomavirus [HPV] as the single most important factor determining the risk of cervical cancer (ACS: Can Cervical Cancer Be Prevented?). HPV, a virus spread by skin-to-skin genital contact, is an incurable infection long considered benign because “in most women, the infection goes away on its own” (STD Facts Human Papillomavirus: Centers for Disease Control). Gardasil, a quadrivalent vaccine manufactured by Merck, which guards against four strains of human papillomavirus, was approved by the FDA on June 8, 2006 and has been approved only for females (FDA Licenses Gardasil: Food and Drug Administration). The vaccine has instigated controversy for several reasons, including the promptness that state legislators drafted bills to mandate this vaccine. Intense lobbying as well as a swarm of advertisements have empowered opponents’ claims that Merck has attempted to get Gardasil included among the mandatory vaccines of many states as a strategy to increase its sales. Adding to the contention is that although this virus affects both males and females, the vaccine was released before it could be approved for men. Most of the complications of HPV are found in females, however, males are the ones giving HPV to women. If both men and women were vaccinated, there would soon be no need for the vaccine. If Merck pushes to vaccinate only women, they are ensuring a constant market for their product. While the controversy surrounding the proposed state mandates are well substantiated, the vaccine could indeed protect countless young women against cervical cancer.

In September 2006, Michigan’s legislators became the first to propose the HPV vaccine as a school requirement, adding to its already thorough sixth grade entrance immunization schedule (National Conference of State Legislatures 2007). After passing with ease in the Senate, the bill encountered problems in the House. In a strange twist of events, the bill passed, and was put to a revote on the last day of legislative session. The nays won, and it appeared that the legislative push in the state of Michigan was finished. Several theories attempt to explain the bill’s failure, from the doubts about the safety and efficacy of the vaccine to concerns about how quickly these bills found their way to the final roll call. Some believed that more time was needed to see how the vaccine worked outside the laboratory. Those who opposed mandatory vaccines in general, spearheaded in the state of Michigan by Mothers Opposing Mandatory Vaccines, believe that compulsory vaccination is a violation of civil liberties. The State of Michigan Department of Education website states that when a child enters school, a record of his or her immunizations may be substituted by a signed waiver that demonstrates the parents’ wishes to not vaccinate their child; opponents called for measures that would make the opt out clause clearer. Despite these concerns, forty-one states and the District of Columbia have either considered or passed legislation regarding mandatory HPV vaccination for girls (National Conference of State Legislatures 2007).

Adding to the debate surrounding the proposed compulsory vaccination is the very nature of the HPV virus. Because it is sexually transmitted, some believe that the vaccine gives young women tacit permission to engage in promiscuous sexual behaviors and that it may advance the belief among youth that there will always be a medicine to fix or prevent the consequences from such activities. Opponents assert that by compelling a mother to vaccinate her eleven-year-old daughter, the mother is passively surrendering her daughter's will to engage in such behaviors at an especially young age. Others argue that if you raise your daughter "correctly," the vaccine will be unnecessary.

Vaccinating against Sexually Transmitted Diseases

Many of the supporters of a school mandate for the HPV vaccine have likened it to the mandated hepatitis B vaccination. Like HPV, hepatitis is spread through sexual contact. However, unlike HPV, which is spread mainly through skin-to-skin contact, hepatitis is spread via bodily fluids (Hepatitis B Fact Sheet: Centers for Disease Control). This means there are ways other than sexual contact to contract the hepatitis virus, such as intravenous drug use or contact with feces (CDC). Today, nearly every state requires vaccination against hepatitis B to attend secondary school, although it is now common for infants to receive this vaccination as part of their pediatric well-visits (Allen).

There are several differences between the school mandate for the hepatitis B vaccine and the consideration to make the HPV vaccine mandatory, the most significant of which is timing. The FDA approved the hepatitis B vaccine in 1986, and Massachusetts, the first state to make the vaccine compulsory for school attendance, did not do so until 1993 (Allen). The years between the vaccine's approval and the bills that mandated the vaccine allowed legislators, public health officials, the pharmaceutical company (who was also, coincidentally, Merck), and the public to observe the efficacy and relative safety of the vaccine, all of which led to little resistance against it. Gardasil, the only HPV vaccine currently on the market, had been approved for fewer than three months before Senator Hammerstrom introduced her bills into the Michigan legislature (Twombly). GlaxoSmithKline's HPV vaccine, Cervarix, will likely soon be licensed by the FDA, which means that because Gardasil is not explicitly named in the proposed bills state legislatures are effectively mandating a vaccine before it even receives its licensure from the FDA. In addition, the hepatitis B vaccine is now given to infants because the virus is spread through feces, which poses a risk to children. We do not know yet if HPV poses a threat to small children, although it is possible. Cytomegalovirus (CMV), which is in the same family as HPV, is widely transmitted in preschool and daycare settings and is so common that by adulthood 85% of the population will have CMV (Willis). Perhaps the largest difference between the mandate of these two vaccines, however, is the fact that the HPV vaccine is only targeted towards women, whereas the hepatitis B vaccine is required for both men and women. It is this discrepancy between the sexes that makes the arguments surrounding the vaccine among the most interesting in health policy.

Girls Only

Of the forty-two legislatures considering HPV legislation today, none include male vaccination in their bill (National Conference of State Legislatures 2007). The FDA reported that Merck's studies of Gardasil were performed on females aged 16-26 and it prevented precancerous lesions and genital warts on female organs resulting from HPV (FDA Licenses Gardasil: Food and Drug Administration). Another study in girls aged 9-15 concluded similarly (FDA). In the five years of Gardasil studies, no testing was performed on males, although both the FDA and Merck report that studies are currently being performed on young men. The urgent

push to vaccinate only women stems from the now demonstrated link between HPV and cervical cancer.

Women in Government, a nonprofit bipartisan organization that works to empower women in positions of governmental power, is one of the vaccine's biggest proponents and has pledged to "eliminate cervical cancer" (Women in Government). Its involvement made the organization the most visible proponent in the push to mandate the HPV vaccine and an easy target for criticism. Opponents assert that money may be Women in Government's primary motivation because, with billions in projected revenue at stake for Merck, some believe that Women in Government is seeking a new donor. It is perhaps because of this criticism that their site makes little mention of their position on mandatory vaccines. Their "What Policymakers Need to Know" brochure strongly encourages the vaccine, yet their mission statement featured in this particular brochure states that "the Campaign supports state legislators' efforts to improve public education about cervical cancer and HPV to help ensure that women have access to the most advanced and appropriate prevention technologies and strategies available" (What Policy Makers Need to Know: Women in Government). Although this demonstrates their support of vaccine education, it fails to mention their opinion on Gardasil legislation. In their grades of individual state's performance in preventing cervical cancer, legislative initiatives proposing a mandate for the vaccine is not taken into account; the categories that Women in Government judges are incidence and mortality, screening, and health care access (State Report on Cervical Cancer Prevention: Women in Government). The only state to receive an "Excellent" rating from Women in Government is Minnesota, which has a Senate Bill pending that would require the HPV vaccination as a prerequisite for middle school entrance for girls. It has not yet passed; the only related act to have passed thus far is a House Bill that requires increased education for girls and their parents regarding the HPV vaccine (National Conference of State Legislatures 2007). Although it is clearly indicated in their "Recommendations for the Prevention of Cervical Cancer" brochure that they believe the HPV vaccine should be required for entrance into middle school for girls, it is not the focus of this document; rather, it emphasizes issues like funding and education (Women In Government Cervical Cancer & HPV Task Force Policy Recommendations for the Prevention of Cervical Cancer).

Gardasil's supporters call it a cervical cancer vaccine, creating the impression that only women are adversely affected by HPV. Although it is true that women suffer more from virus related complications, HPV can cause ailments in men, including anal and penile cancer (Human Papillomavirus and Cancer Q & A: National Cancer Institute). These problems from the virus are so uncommon in males, however, that there is now not even a test to determine if a man has HPV (Koebler). For women, yearly Pap tests are strongly recommended because the virus can lead to dangerous complications, and those women whose tests come back inconclusive are given a more thorough test that screens specifically for the HPV virus (HPV Test). The more tangible proof of HPV in women makes the virus seem deceptively more common in them, leading to the misconception that HPV is a woman's disease and that the vaccine would be necessary only for women.

Some sources report that an HPV vaccine has been studied in men as early as 2004, and media relations representatives at Merck have reported that the FDA may approve men for an HPV vaccine as early as 2008 (Koebler). Although men rarely face problems because of the virus, a vaccine for men is still in the best interest of preventing HPV. Even though men are at a "low risk" of contracting the virus, about fifty percent of men at a given time have HPV, with one percent currently with genital warts, and an eighty percent estimated lifetime risk for contracting genital warts (STD Facts). HPV-related cancer risks between men and women are not even comparable; cervical cancer affects 13,000 American women annually, while the

number of cases of penile cancer in 2006 was just above 1,000 (HPV Vaccine Studied for the First Time in Men). Cancer is of much greater concern than genital warts, and the emasculating characteristics of penile cancer makes an unfortunate situation embarrassing, so male cancers have not been able to garner the support that female cancers have. The higher cancer levels make women appear to need more protection. Nonetheless, women acquire the virus from men, so if men were likewise vaccinated the virus would be virtually eradicated.

Because of society's unfair sexual double standard, the HPV virus appears a woman's disease. The natural receptiveness of intercourse makes women more vulnerable to venereal diseases and sexually transmitted infections like HPV. Also, women bear the most obvious sign of unprotected sex, pregnancy. Because signs of promiscuity are more apparent in women, some consider sexually transmitted diseases and pregnancy as punishment for illicit actions. For males, high levels of sexual activity are considered biologically natural, and most men show few obvious signs of their promiscuity. The only groups of males with high incidences of sexually transmitted infections are men who engage in sexual actions with other men, another form of behavior considered immoral by some.

Those who resist mandating the HPV vaccine argue that protecting women against HPV will increase promiscuity, suggesting that protecting women from a sexually transmitted virus would give them consent to engage in unsafe sex. This accusation plays again on the stereotypes surrounding female sexuality. HPV can be transmitted even if a woman takes prophylactic cautions during intercourse. This virus is spread through skin-to-skin contact, and latex condoms leave a large portion of potentially infected skin exposed (Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease Prevention). Moreover, it is not necessarily only promiscuous sex that causes a woman to get HPV. It is entirely possible for a woman to have only one partner her entire life, use protection every time, and contract HPV in her marriage bed. The increased promiscuity theory is also debunked by common sense; the elimination of one sexually transmitted disease does not alleviate a woman's fear of pregnancy, gonorrhea, syphilis, pubic lice, or HIV/AIDS. Marketing the HPV vaccine to both men and women would double Merck's revenue, which is in the best interest of any pharmaceutical company, especially one still under scrutiny for their "bad drug," Vioxx, only a few years ago (Allen, Rubin). In fact, several opponents of both the school mandate and even the vaccine itself have argued that monetary greed is responsible for Merck's intense lobbying for government-sponsored immunization.

Common Cents

Gardasil is an expensive vaccine, with the three-series regimen costing \$360. Because of its relative newness, only a few insurance companies have decided to cover it (Fiegan). As it now stands, the vaccine is on the CDC's list of recommended vaccines, so that it may be covered by the Vaccines for Children, which provides no-cost vaccines for qualifying children under the age of eighteen (Some Parents Have Difficulty Gaining Access to Insurance Coverage for HPV Vaccine Gardasil). If this vaccine is mandated, the poor and uninsured will have access to get this vaccine for their children, while working poor and lower middle class will feel the burden of the expensive vaccination. For underinsured families and those who make too much money to qualify for programs like Michigan's MICHild, an expensive vaccine is a potential financial heartache. These families could opt out of vaccinating their children, which would create a class of people not protected against HPV.

Assuming that the school mandate becomes law, it is not unlikely to think that more insurance companies will cover the vaccine. Compulsory vaccination means the number of people receiving the vaccine will greatly increase, especially if the FDA approves the vaccine for males.

Another possibility is that state legislatures may enact laws to force the insurance companies to cover the shots. Arizona, California, Illinois, Iowa, Nevada, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, and Virginia have all either proposed bills or have passed bills requiring insurance providers in that state to expand coverage to include the HPV vaccine (National Conference of State Legislatures 2007). In addition, some states are considering bills that would reallocate funds for HPV awareness and prevention. For instance, Colorado has reallocated “four percent of state tobacco settlement money into the cervical cancer immunization fund” (National Conference of State Legislatures 2007).

Merck’s Motivation

Although the FDA has judged Gardasil effective, some critics still debate its safety. In her testimony to the House floor, Michigan Representative Zelenko criticized Merck, saying that if “they were really interested in vaccine efficacy in children, [it] should be studied properly in children” (State of Michigan House of Representatives 2006 Journal No. 95). The FDA approved the vaccine for girls as young as nine, and the state bills require vaccination at age eleven. The youngest girl tested in the Gardasil studies was fifteen, creating concern among skeptics, because the bodies of most nine and fifteen year olds are vastly different. It is also not yet known if those who receive the shot will need a booster. Representative Zelenko and many others opposed to this school mandate insinuate that Merck’s lobbying efforts seem suspiciously aggressive. Like all other aspects of this story, opponents believe money, not the public’s health concerns, motivates Merck.

Texas was the first state to mandate HPV vaccination for young girls, and it did so through Governor Rick Perry’s Executive Order (O’Beirne). This was a remarkably unexpected move; the Republican governor of a conservative state bypassed his own legislature to enact a vaccine mandate for a drug that prevents a sexually transmitted infection. Although Merck has declined to say how much money they have donated to special interest groups like Women in Government or to lobbyists, there was speculation that the drug company doubled the amount of money it was spending on lobbyists in Texas to as much as \$250,000 (Merck Lobbies for HPV Vaccine to Become Law). Providing even more fuel for criticism, Merck’s most powerful lobbyist in the lone star state was Mike Toomey, Governor Perry’s former Chief of Staff (Merck Lobbies for HPV Vaccine to Become Law). Almost immediately after Texas mandated the vaccine, Merck halted its lobbying efforts (Pollack and Saul). Although the executive director of medical affairs for Merck’s vaccine division, Dr. Richard Haupt, said that the company decided to stop lobbying because “school requirements and Merck’s involvement in that are being viewed as a distraction” to the goal of reaching as many females as possible, the decision to stop so soon after Governor Perry’s executive order only made the situation seem peculiar (Pollack and Saul).

According to the company, GlaxoSmithKline’s proposed HPV vaccine, Cervarix, will be licensed later this year. Cervarix is bivalent, meaning that it only protects against strains 16 and 18, which are responsible for seventy percent cervical cancer, while Gardasil is quadrivalent, meaning that it also protects against strains 6 and 11, which are responsible for ninety percent of genital warts cases. Cervarix may be the more acceptable of the two vaccines since it only protects against strains of the virus that cause cancer.

The impending competition between these two companies has already begun with an unprecedented trial conducted by GlaxoSmithKline. In this study, GlaxoSmithKline is administering Merck’s Gardasil to half of the study’s over one thousand subjects, while the other half receives Cervarix. GlaxoSmithKline will then monitor their immune systems, and the vaccine that stimulates the higher response will be deemed the more effective (Ginsberg). Although competitive trials like this are common for drugs, this one has high stakes because of

the promise of the projected \$2 to \$4 billion in HPV vaccine revenues over the next two years (Ginsberg). The projected revenue is so large, due in part to Merck's successful "One Less" advertising campaign.

Merck has marketed Gardasil in a way that no pharmaceutical company has previously done. While this is certainly not the first nationwide campaign for a drug, the "One Less" campaign is by far the largest for a vaccine, with advertisements on the radio, commercials in primetime television shows, and full page ads in popular magazines. Merck has marketed Gardasil to individuals, targeting young women and their mothers instead of their physicians. While most pharmaceutical companies' sales representatives court doctors with lavish dinners and gifts, Merck has stylishly crafted their advertisements to appeal to the emotions of its intended consumers. Gardasil's advertisements make young women forget about sex as it sells a vaccine for a sexually transmitted virus. The girls featured in TV and radio ads are strong and vibrant, and they pledge to be "one less" woman affected by cervical cancer. One advertisement features a skateboarder, a basketball player, and a drummer in a rock band, brashly telling the camera that they know enough to make the simple choice to become "one less woman affected by cervical cancer." Other versions of the commercial show similar girls, all who convey intelligence, athleticism, and strength. Sexuality never crosses the viewer's mind in seeing these women. Their clothing is baggy, no one is wearing makeup, and all the girls look like they could have sat in the corner of your homeroom class. Opponents of adding Gardasil to the list of mandated vaccines claim that it is only necessary for women who will be promiscuous, so by using girls who seem preoccupied with things other than sex, Merck demonstrates that Gardasil is for everyone, even prudish tomboys. The women in this commercial only mention the name of the virus once, while mentioning "cervical cancer" seven times, even referring to Gardasil as "the only cervical cancer vaccine" at the end of the one minute television ad.

The mothers in these commercials also play a crucial role; they deliver the message about the potential risks of the vaccine. While their daughters exhibit mature behaviors, possessing the intelligence to fully protect themselves against a potentially life-threatening disease, the more mature women in the commercials, who we assume are the girls' mothers, offer warnings: "Gardasil may not fully protect everyone." Portraying mothers as the reluctant party makes the vaccine more appealing to both mothers and their daughters. Merck is encouraging the choice to vaccinate while still hoping for state mandates for compulsory vaccination. As more people choose to vaccinate, there will be more support for the state mandates.

The mother-as-protector angle is also exploited in Gardasil's full page magazine ads. In bold letters it reads "Get your daughter vaccinated as a girl. Help prevent her from getting cervical cancer as a woman." The ads have been running in several magazines, including Ladies Home Journal, Redbook, and Woman's Day, magazines marketed to middle-aged women, with their articles dealing with motherhood and marriage. Gardasil's ads rarely appear in magazines that the women actually receiving the vaccine would read, such as Cosmopolitan or Seventeen. Middle aged mothers are the staunchest opponents of the state mandates, and Merck aims their advertisements toward this demographic in a hopeful attempt to gain support for the compulsory vaccine legislation.

What it All Means

Gardasil has been proven safe and effective in all of its studies and is now licensed for sale by the FDA (FDA Licenses New Vaccine for Cervical Cancer). This does not always mean that FDA-approved drugs that are completely safe, as the recent problems with Vioxx demonstrate. Keeping this in mind, it is easy to see why many are skeptical about a vaccine that could be

mandated for all young girls only months after its licensure. HPV is not a life-threatening epidemic like polio, where the urgency to vaccinate may have been necessary.

Michigan legislators have recently reintroduced a proposed school mandate for the HPV vaccine. In May 2007, the Senate passed SB 416, which states that parents must be informed about the potential dangers of the virus and “the availability, effectiveness, and potential risks for vaccination of human papillomavirus, and sources where parents may obtain additional information and may obtain vaccination of a child against human papillomavirus.” The bill stirs little controversy because it only seeks to educate parents about HPV and the vaccine; it does not require vaccination. Another similar bill, introduced by Democrats in the House on October 17, only requires education as well and was referred to the Committee on Health Policy on the same day it was introduced. The other bills, two in the Senate and two in the House, seek to mandate the HPV vaccination for girls entering sixth grade and have sat stagnant since the end of January 2007. Although the bills that would require vaccination have seen little action, the introduction and passage of the bills requiring parents to become notified and aware of the vaccine is a potential first step toward a school mandate. Most state legislatures’ sessions have now ended, but several, including those California, Connecticut, Florida, Maryland, Mississippi, and South Carolina, have bills with school mandates either withdrawn or that have died in session (National Conference of State Legislatures 2007). Colorado, Illinois, and Washington, have bills similar to Michigan’s that only require parents to be aware of the HPV vaccine, and these bills have passed. Virginia, which has made the vaccine a school-entry requirement for sixth grade girls, and New Jersey, which requires vaccination sometime between seventh and twelfth grade for girls, have also been successful in passing legislation (National Conference of State Legislatures 2007). In Texas, although the Executive Order mandating the HPV vaccine was overturned by the legislature, new bills have been reintroduced to create a school mandate in both the Senate and the House (National Conference of State Legislatures 2007). Also, a bill that requires schools to pass out literature regarding the HPV vaccine in both English and Spanish has passed, and went into effect on September 1, 2007 (National Conference of State Legislatures 2007).

The contention surrounding Gardasil and the legislation that it has inspired is far from over. In an era of renewed morality, opponents see this vaccine as a temporary fix for a complex problem. The debate surrounding the HPV vaccine mostly comes from the fact that the virus is sexually transmitted. Adding to the contention surrounding the vaccine is Merck's apparent enthusiasm for mandatory vaccination, and their focus only on females. It is Merck's economic self-interest to ensure that only young girls are vaccinated against HPV. As long as there exists a pool of infected or potentially contagious young men, women will need the HPV vaccine to protect themselves from the virus and its causes. Mandating the vaccine for both males and females would ultimately wipe out the virus and eliminate the need for the vaccine.

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Spectacle and Respect

James L. Nelson, Ph.D.
Philosophy Department

I missed the recent display of plastinated bodies at the Detroit Science Center that was the subject of thoughtful discussion by Profs. Goldstein, Mongoven, and Waller in the last MHR, although I did see a similar exhibit in London--Body Worlds--in 2002. I walked away with a more vivid appreciation of the Scriptural notion that we are “wonderfully and fearfully made”--but also with the sense that I had been exposed to an upmarket version of an old-time carny side-show--oddly fascinating and vaguely guilt-inducing. Side-shows trouble me because I suspect that responding to people wholly as spectacles is inconsistent with the respect they are owed; a similar concern drove my discomfort in London.

Something in the neighborhood of this worry seems touched on in Prof. Mongoven’s sensitive remarks on humanizing and de-humanizing bodies, but her dominant moral concern seems to be with whether informed consent requirements had been fully complied with, and something similar might be said about Prof. Waller’s fascinating account of the history of human anatomy. Giving consent pride of place seems to me reasonable but ultimately misleading--a point Prof. Goldstein’s claim that “There is no inherently right or wrong way to treat a dead body, except within a particularly cultural setting” helps explain. The connection is this: we worry primarily about informed consent in “Body Worlds” type cases because that’s the only pertinent moral notion that seems rationally defensible--anything else would be like turning mere taboos into categorical imperatives.

Yet informed consent is not a basic moral notion; it is important because it expresses the respect owed to beings of our kind. Nor is consent so straightforwardly applicable here--we are, after all, talking about dead people. So if it makes sense to be concerned that the self-regarding will of a person no longer alive was violated, we seem to have accepted the notion that death doesn’t render a person invulnerable from wrongful disrespect.

This doesn’t worry me much, but we don’t really need to go down this road. All we need do is allow that there’s moral reason to express some kind of attitude of respect to human remains. Here I dissent from Prof. Goldstein’s claim. Consider a culture that treated human bodies--say, the bodies of their poor--with frank contempt, perhaps grinding bones and viscera to make premium kitty litter. Such actions, in my view, would be ethically defective and perhaps just flatly wrong, even if calmly accepted in that culture. Culture does, however, become key when we’re trying to decode the local “idioms” of respect and contempt: if a given culture worshipped

cats as gods, human kitty litter might be just fine--but then such use wouldn't be a sign of contempt.

The questions that displays of plastinated bodies leave with me is whether anyone ought to consent to be so used after death, whether anyone should seek out such consent. Both that such questions are open, and that we tend to neglect them in favor of talk about consent, shows how obscure our own moral resources remain to us--suggesting, perhaps that the deepest lessons we have to learn from these peculiar side-shows is not scientific nor aesthetic, but ethical.



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Traveling Bodies and Renaissance Anatomical Theater

by David Kozishek, M.A., B.C.C.

A significant conceptual turn took place in the history of human anatomical dissection in Renaissance Europe from the 16th to the 18th centuries. During this time, several developments took place within the revival of the humanist tradition that laid the groundwork for the modern practice of anatomical dissection. First, illustrated works on anatomy were written and translated into vernacular languages so that they could be read and understood by people who had not received training in classical languages. Second, anatomical dissections were conducted in either churches or specially built theaters that allowed for banked, circular seating around a center stage where dissections took place. Front rows of seating were normally reserved for medical personnel, but the dissections were also open to the public who were charged an admission fee. These public events were conducted with great ceremony and drama, often bordering on the liturgical or theatrical. Third, in keeping with the Renaissance Humanist ideal of learning from direct experience (rather than learning from an uncritical acceptance of authoritative--but often inaccurate--sources), the anatomist would conduct dissections himself. In the past, medieval professors of anatomy would read from an authoritative text of the time (for example, the work of Galen) while someone else performed dissections for his students. This severance of knowledge and experience prevented the practice of anatomical dissection from fully informing theories of medicine of the time. These first three developments were enmeshed with a fourth; public anatomical dissections came to be seen as a means to acquire self-knowledge (previously known only to the creator of humanity), and to remind people of how fleeting life is (*memento mori*). The Renaissance artists and anatomical illustrators reflected these developments in their art as they strove to create an aesthetic experience for the viewer/reader out of what was a bloody and violent spectacle. Science, education, art, drama, religion, and public spectacle were comingled in a way not easily teased apart.

Today, exhibits such as Gunther von Hagens' *Body Worlds* and *Our Body: The Universe Within* can be seen as participating in many of these same themes. The contemporary exhibits are presented as public events that are primarily educational in nature, but that also partake in drama and theatrical presentation. Like anatomical dissections of the past, the exhibits quite literally allow us to look inside other bodies in order to learn and wonder about our own. Human dissections in the Renaissance and our contemporary traveling exhibits also share more shadowy elements such as ethical concerns about how the bodies were obtained, whose bodies they were,

lack of reverence for the lives that were lived in those bodies, and the fact that there was/is profit to be made by charging the public for admission.

But there are also some clear and important distinctions to be made between the Renaissance practice of human dissection and today's traveling exhibits. Two in particular are important to keep in mind. First, the theatrical context for dissections in the Renaissance provided the setting for the primary goal: learning. Today, the inverse seems to be true; traveling bodies are exhibited in an educational context (museums) for a primary purpose that, I would argue, is dramatic entertainment meant to shock and awe crowds of paying visitors. Having spent time at *Body Worlds* when it opened in Houston, I came away with the impression that the exhibit was primarily intended to entertain by presenting bodies in fantastic poses, and that the primary goal was being presented under the guise of a more noble and acceptable endeavor: anatomical education. Second, dissections in the anatomical theaters of Renaissance Europe took place in real time accompanied by all of the sights, sounds, and smells of dissecting a recently dead human body. This very real sensory participation by the audience in what was happening before their eyes undoubtedly served to educate (and perhaps, shock and awe) the participants in a way that static, posed, plastinated bodies cannot. Much of our contemporary world now consists of plastic--perhaps it's not surprising that we are flocking to see a discovery that allow us to plastinate the experience of death itself. The progressive distancing of ourselves from the experience of death is perhaps the most profound difference between today's traveling exhibits of bodies and the Renaissance Europe anatomical theater.

Note:

My historical reflections are primarily drawn from: Mary G. Winkler, "The Anatomical Theater" *Literature and Medicine* 1993;12(1):65-80.



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News & Announcements

Judy Andre

- Presented (with Ann Mongoven) “A Multi Faceted Public Health Curriculum,” for the Association for Practical and Professional Ethics, mini-conference on Public Health Ethics, in San Antonio (Feb).
- Published entries for the Encyclopedia of Business Ethics and Society: “American Medical Association,” “Developing World,” and “Productive Efficiency” (2007).

Libby Bogdan-Lovis

- Was nominated and elected to the Advisory Board for the Cochrane Developing Countries Network (CDCN), a newly developed entity of the International Cochrane Collaboration. In this position, she will provide both strategic advice and support, and monitor developing country participation in the CDCN.
- Presented “Is Health Care a Right: Costa Rica and the Development of the Health Care System” for the College of Human Medicine Office of Admission’s freshman seminar series (Jan).
- Represented the Bioethics, Humanities, and Society Program at the 26th Annual National Conference of the United States Hispanic Leadership Institute, Chicago (Feb).
- Was a “talk back” panelist at the East Lansing premiere screening of the recently released documentary “The Business of Being Born” (February).

Sean Brotherton

- Presented “Socialist Entrepreneurs, Emergent Capital, and the Biopolitics of Health in Contemporary Cuba” at the American Anthropological Association Meetings, Washington, D.C. (Nov/Dec).
- Presented “Socialist Body Politics: Macroeconomic Change, Emergent Capital, and Expanding Therapeutic Itineraries in Cuba’s Special Period” to University of California - Davis, Department of Anthropology (Jan).
- Presented “Machinations of the State: Emergent Capital, Socialist Entrepreneurs, and Bodily Practices in Cuba’s Health Sector” to Yale University’s Department of Anthropology, New Haven, CT (Jan).
- Co-Chaired Session (with Elise Andaya) titled Healthcare in Contemporary Cuba, at the International Symposium: A Changing Cuba in a Changing World at the Bildner Center for Western Hemisphere Studies, The Graduate Centre, City University of New York (Mar).

Leonard Fleck

- Published, with Karen A. Petersmarck. 2008. Ethical Considerations Related to Obesity Intervention. In Obesity in Childhood and Adolescence, Vol. 2. Understanding development and prevention, ed. Hiram E. Fitzgerald and Vasiliki Mousouli. West Port, CT.: Praeger.

- Gave a lecture, “Confidentiality: Difficult Cases and Difficult Judgments,” in December at NIH (Washington, D.C.) under the auspices of their Clinical Bioethics Center (Dec).
- Did a workshop, with Tom Tomlinson for physicians and nurses at Spectrum Health in Grand Rapids. Tom’s lecture was “Ethical Issues in Withdrawing and Withholding Life-Sustaining Care.” Len’s lecture was titled “Futility: Ethical and Policy Challenges” (Jan).
- Presented “Research Ethics: Contemporary Challenges for Faculty and Students” Did a lecture in February for graduate students in genetics and microbiology at MSU titled (Feb).
- Gave four lectures for the Provincial Health Ethics Network in Edmonton Canada at various hospitals. The titles of two of those lectures (repeated) were: “What Does an Ethical Organization Look Like?” and “When Health Care Providers Experience Distress: The Importance of Moral Space” (Mar).

Margaret Holmes-Rover

- Was appointed to the External Scientific Advisory Board of the Maine Medical Center, Portland, Maine.
- Published (with co-authors R.W. Martin, A.F. Head, J. Rene, J. Swartz, J.J. Fiechtner, B.A. McIntosh). Forthcoming Patient Decision Making Related to Anti-Rheumatic Drugs: The Importance of Patient Trust of Physician. *Journal of Rheumatology*.
- Published (with co-authors S.N. Whitney, H. Brody, C. Schneider, L.B. McCullough, R.J. Volk, A.L. McGuire). Forthcoming. Beyond Shared Decision Making: An Expanded Typology of Medical Decisions. *Med Dec Making*.

Ann Mongoven

- Presented “An Integrated Public Health Ethics Curriculum” at the Association of Practical and Professional Ethics national meeting in San Antonio, Texas. She also moderated a panel on ethical issues in mental health care at the conference (Feb).

Tom Tomlinson

- Went on a recruiting visit to Tuskegee University and meet with the students and faculty of the Tuskegee University National Center for Bioethics in Research and Health Care. Presented “Caring for Risky Patients: Duty or Virtue?” and “Ethical Issues in the Use of Archived Biological Materials” (Jan).
- Did a workshop, with Len Fleck for physicians and nurses at Spectrum Health in Grand Rapids. Presented “Ethical Issues in Withdrawing and Withholding Life-Sustaining Care” (Jan).
- Presented “Caring for Risky Patients: Duty or Virtue?” at the Center for Healthcare Ethics, Cedars-Sinai Medical Center, Los Angeles (Feb).