Setbacks and Steps Forward in the Search for Safe and Effective Microbicides

By Bindiya Gillenwater Patel, MPA

Worldwide, women are disproportionately impacted by the HIV/AIDS epidemic. More women are newly infected with HIV than men, primarily through having sex with men who are HIV-positive. In the U.S., more than 250,000 women are living with HIV/AIDS, and the disease is the number one cause of death among African American women aged 25-34. And, internationally, around half of the 38.6 million people living with HIV are women. For this reason, advocates around the world have long voiced the need for an HIV prevention method that women can control. (See the box on page 3 for more information about women and HIV/AIDS.)

Microbicides — products that are designed to be used in a gel, tablet, or vaginal ring to help prevent HIV/AIDS — could provide exactly that. Due to advocates’ work around the world, and the recent attention on microbicides at the 2006 International AIDS Conference in Toronto, millions of people have heard about microbicides. The challenge the field now faces is to find the correct balance between building enthusiasm and political support for microbicides, while avoiding raising unrealistic expectations in the media or in our outreach work.

Microbicides are not going to be a magic bullet against HIV. It is important to note that, while microbicides will help people reduce risk of infection, they will never be as effective as condoms. We still need to improve people’s access to the interventions that we know work now: making sure that male and female condoms are available and affordable (for more on this, see: www.preventionnow.net, as well as http://www.populationaction.org/resources/publications/condomscount/index.htm); ensuring that pregnant women get access to services that prevent maternal transmission to their babies (www.pedaids.org); and promoting appropriate male circumcision programs (http://www.global-campaign.org/malecircumcision.htm).

Nonetheless, microbicides have the potential to be an important way for women and couples to reduce their risk of infection. The hope is that couples will be able to use microbicides more consistently than they currently do condoms. We need to encourage people to continue to use condoms if they possibly can, and suggest additional use of microbicides for back-up protection and added pleasure.

Timing for Microbicide Availability

Although microbicides do not yet exist, ten products are currently being tested in clinical trials, and anticipation is building: results from the first microbicide effectiveness trials could be available in 2008. (See page 7 for a chart of products undergoing large-scale human effectiveness trials.) Then it will take at least one or two years for the products to be reviewed and approved. Thus, while a microbicide could be ready for introduction by 2010, it’s likely only to happen in a...
Getting the Health Care We Need, Instead of the Products Someone Wants to Sell

by Cynthia Pearson, Executive Director

Reading the articles in this issue has made me think a lot about how often our health care becomes distorted away from its essential purpose - to care and to support health. Instead, our visits with health care providers and our awareness of health issues are heavily influenced by the marketing of profitable products. Take statins, for example. These cholesterol-lowering drugs are among the most heavily used medications in the U.S. It's hard to watch T.V. without seeing an advertisement for one of the many statins on the market. These ads imply high cholesterol alone is enough to make taking a statin worthwhile, and that men and women benefit equally. Not so! In her article on page 4, Electra Kaczorowski explains what studies have and haven't shown about the effectiveness of statins in women, and concludes that a focus on health would lead to a dramatically different approach to preventing heart disease.

The new HPV vaccine is another example of marketing going way beyond the real need for the product. Alicia Bell's article on page 8 does a great job explaining what the HPV vaccine can and can't do to improve the health of young women and reduce the likelihood of developing cancer. A slow and sensible approach to introducing this vaccine in the U.S. would make sense for many reasons, but that's not what's happening. Instead, the manufacturer of this vaccine is pushing hard for millions of young women to get the shot in the next few months, as part of school vaccination programs. Why the rush? It seems pretty obvious to us that the manufacturer wants to corner the market before another vaccine is approved. In fact, the FDA is reviewing another HPV vaccine for approval right now.

The fact that we don't yet have a safe and effective microbicide for women to protect themselves against HIV/AIDS and other sexually transmitted infections is another painful example of how the development of products we need takes a back seat to companies' focus on products with a large profit margin. Bindiya Patel's cover story about microbicides explains how dedicated researchers working in respectful collaboration with activists can come up with exciting new products and ethical approaches to testing them in women. But, and this is a very big but, it's 20 years after women started talking about the need for a microbicide, and we still don't have one. Funding for microbicidic research has come mostly from the government and private foundations - and it hasn't been nearly enough. The pharmaceutical industry could have seen this need, thrown their resources into the problem and gotten products to market years ago. But most big pharmaceutical companies believe that the market for HIV protection won't be profitable, and have been slow to act in this field.

As we raise women's voices for health care for all, let's keep talking about what health means to us and what we really need - and keep working to make that a reality for all women!
Microbicides

A few countries, most likely through smaller scale, introductory programs. If the products currently in effectiveness trials do not prove effective, the timeline will be longer. There are several second-generation leads already in human testing, and we need to ensure that the entire pipeline of products advances.

In January, 2007, however, the search for an effective microbicide faced a major setback when the trials of one potential product were stopped due to safety concerns. Shortly thereafter, in March 2007, the U.S. House of Representatives and Senate both introduced legislation to provide a much-needed boost to the microbicides field. We'll discuss both of these developments below.

Cellulose Sulfate Trials Close Due to Safety Concerns

In order to fully understand the recent microbicide trial closures, a bit of background information on clinical trials is useful. Before any new drug is available to consumers, it goes through a rigorous series of clinical tests in people. The first two levels of these safety tests, called Phase 1 and Phase 2 trials, look for evidence that the product could be harmful. If a product gets through Phase 1 and 2 safety trials without evidence that it might cause harm, it can then move to Phase 3 effectiveness trials, which compares the new product to a standard product or a placebo. The microbicide gel cellulose sulfate (CS) went through 11 Phase 1 and 2 trials, without results to indicate that it was harmful. CS proceeded to Phase 3 trials, in which one group of women used the experimental gel (CS), while a second group used a placebo gel without the active ingredient.

Extensive measures are taken to help all microbicide trial participants understand that they should not count on the gel for protection from HIV, that half would receive the placebo gel, and that they have the right to withdraw from the trial at any time. All participants receive monthly HIV prevention counseling, free condoms, and prompt diagnosis and treatment for any sexually transmitted infections. Finally, an independent Data Safety Monitoring Board (DSMB) exists for each microbicide trial. The DSMB is composed of individuals with expertise in statistics, medicine, clinical trials, and community issues; it serves to protect participant safety and recommends whether a particular trial should continue.

Cellulose sulfate was one of four microbicides in Phase 3 effectiveness trials for HIV/STI prevention (the other three are BufferGel, Carraguard, and PRO2000). CONRAD was conducting Phase 3 trials to assess CS’ effectiveness in Benin, India, South Africa, and Uganda. A similar trial, sponsored by Family Health International (FHI), was also underway in Nigeria. Both sponsors are U.S.-based nonprofit research groups dedicated to advancing health in developing countries. In January, at the recommendation of their respective DSMBs, both groups discontinued their CS trials after CONRAD’s DSMB found evidence suggesting that the microbicide might be contributing to an increased risk of HIV infection. (In other words, more HIV infections occurred in women using the experimental gel than among women using the placebo.) Although review of the data from the Nigerian trial found no evidence of increased risk, FHI felt that the only responsible course of action was to halt its study also. Interim results of the other three ongoing Phase 3 trials have been reviewed by their respective DSMBs, which have found no evidence of similar safety concerns.

Once their trials closed, the FHI and CONRAD investigators quickly shifted their efforts to notifying the trial participants, collecting any unused gels, and ensuring that participants received appropriate follow-up care — including counseling, HIV testing, and medical referrals, if needed. In response to demands from advocates, many trial sponsors now develop written agreements before trials begin. In this case, both trial sponsors had prepared written agreements in advance with local providers to assure that any women infected while enrolled in the trial would get ongoing care and treatment.

In the days following the closure of the CS trial, women from around the world voiced a strong demand for information about what went wrong with these trials and support for continuing the search for a safe, effective microbicide. Women still don’t have the tools they need to protect themselves from HIV. The Global Campaign for Microbicides and the

Women and HIV

Women are at higher risk of HIV infection than men partly because of biology, partly because of economics, and partly because of culture. Women are more vulnerable to HIV because they are exposed to more virus for a longer period of time during sexual intercourse. Young girls are especially at risk because their reproductive tracts are not fully mature and are more vulnerable to infection.

Economically, women often have less access than men to education, job opportunities, property, or credit, which makes them financially dependent on their partners.3 As a result, women often cannot afford to leave relationships that put them at risk of HIV and other STIs, to refuse sex, or demand condoms. Culture also plays a role. Here and abroad, women are expected to be faithful but men are not, and their male partner’s infidelity is one of the greatest HIV risks women face. In addition, gender-based violence is a big factor in women’s risk.6

The current prevention methods (abstinence, fidelity, and condom use) often require active acceptance, participation, consent and cooperation by both partners. But women don’t always have control over when and how they have sex. While we are making important progress on delivering treatment, we still need to do everything we can to give people more prevention options — especially those that they themselves can control. Microbicides provide an alternative for women who ask, “I just can’t make him use a condom; isn’t there something else I can do to protect myself?” Once microbicides become available, we’ll be able to tell her that, while the new products aren’t as effective as condoms, they’re much better than nothing. And, as we all know, a lot of women are getting infected because “nothing” is all they have.
Exploring Statins: What Does the Evidence Say?

By Electra Kaczorowski

Statin drugs are the best-selling class of drugs in the U.S. These medications (sold under the brand names Lipitor, Crestor, Pravachol, and Zocor, to name a few) block an enzyme in the liver that aids in the production of cholesterol, thereby reducing cholesterol levels and, hopefully, rates of coronary heart disease (CHD). Most of the cholesterol in the human body is produced by the liver; we also get smaller amounts from our diet. Between 1987, when the Food and Drug Administration (FDA) approved Mevacor, the first statin, and 2002, statins became one of the most widely prescribed class of drug in the U.S., with 13.1 million monthly prescriptions from June 2006—December 2006.¹

With tens of millions of people — most of whom are healthy — taking statins daily, important questions must be asked. Who have statins been proven to do? What do they prevent or treat? Who is taking them? What benefits from them? How do women fit into this picture? Although the answers to all of these questions should have been established long ago, they remain unclear, inconsistent, and largely unavailable to the public.

The Role of Cholesterol in Coronary Health

What is the connection between high cholesterol and heart health? Cholesterol is a waxy substance found in the lipids (fat) in our bodies. It plays an important role in our health, such as in brain function and hormone development. Cholesterol is transported through the body by attaching itself to different proteins. Many kinds of proteins transport cholesterol — the two that get the most medical attention are “high-density lipoprotein” (HDL) and “low-density lipoprotein” (LDL). HDL cholesterol (the so-called “good cholesterol”) is the term used for cholesterol that is transported away from the arteries. LDL cholesterol (“bad” cholesterol) is transported through the body to the arteries near the heart and the brain, causing a build up of white blood cells and other matter, collectively referred to as “plaque.” The Framingham Heart Study, launched in 1948 and continuing today, established that high LDL levels are a risk factor for coronary heart disease. (The study also found that several other modifiable risk factors have an impact on coronary health. These include smoking, high blood pressure, diabetes, physical inactivity, and obesity, and are just as critical to address as an individual’s cholesterol levels.) Complicating the issue is the fact that it remains unclear what a healthy level of LDL is in the first place — and how varying LDL levels impact overall health, including coronary heart disease, in people of all ages.

Just the Facts: Statins’ Effect on Heart Disease & Cholesterol

Statins are often reputed to be miracle drugs — safe, effective tools against heart disease, dubbed America’s leading killer. Why is CHD a major health problem, and statins do provide effective treatment for some, the facts are not so simple, however.

Coronary Heart Disease (CHD)

CHD (also known as coronary artery disease, ischemic heart disease, or simply heart disease), is a condition that develops when the arteries that supply blood to the heart (the coronary arteries) harden and narrow due to the buildup of plaque. This process is called atherosclerosis, and can occur normally as a person ages.

Atherosclerosis results in reduced amounts of blood and oxygen reaching the heart, and can sometimes cause blood clots which altogether block the heart’s blood supply (commonly referred to as a heart attack). CHD can be diagnosed using a variety of different tests, including an electrocardiogram (EKG), an echocardiogram, or X-rays.

The major risk factors for CHD that can be controlled are: smoking, high blood pressure, high blood cholesterol, obesity, and diabetes. Risk factors that cannot be changed or controlled are: age and family history of CHD or personal history of a cardiac event.

There are two ways in which statins can affect heart disease: through primary prevention or secondary prevention. Primary prevention refers to risk reduction of cardiac events, such as angina (chest pain), heart failure, or heart attack in individuals who do not have heart disease; secondary prevention refers to risk reduction among those who have already been diagnosed with CHD.

The evidence for secondary prevention is stronger than that for primary prevention. Statins clearly reduce the risk of subsequent heart attacks for both men and women with CHD. But, reducing the risk of recurrent CHD is not the only goal; it is also important to look at death rates from CHD and other causes. Here, the results for men and women differ: statins reduce men’s risk of dying from a heart attack and the overall mortality rate, but the available evidence suggests that they don’t have an effect on either of these factors in women.

When it comes to primary prevention, the evidence gets a bit murkier. Clinical trials have shown that statins reduce the rate of CHD in men with a very high risk of developing the disease (we do not have enough evidence to make the same claim for women). But, the drugs still do not provide as much risk reduction as the public has been led to believe. For every 50 high-risk men aged 30-69 who take statins for five years, a cardiac event will be prevented for only one of them.¹ In men and women with a moderately elevated risk, statins reduce the risk of CHD, but do not decrease overall mortality. In this population, statins also appear to increase the risk of developing other serious diseases, such as cancer.

Faulty Guidelines for Statin Use

The widespread use of statins was immeasurably boosted by revisions of the National Cholesterol Education Program’s (NCEP) guidelines. NCEP, a national effort to educate the public on the dangers of high cholesterol, is sponsored by the National Heart Lung and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH). In 2001, and again in 2004, NCEP updated its
physician guidelines with recommendations that patients who either have coronary heart disease, or are at moderately elevated risk for developing it, should substantially reduce their LDL cholesterol. The guidelines outline specific cholesterol screening practices for physicians, and recommend statin therapy if lifestyle changes have failed to sufficiently reduce cholesterol levels.

As noted, these guidelines were recently expanded again in 2004. One update is the recommendation of achieving even lower levels of LDL (70mg/dL) for patients identified at very high risk of CHD (including those who already have the disease). Another change is the suggestion that those at moderately high risk (individuals who have two or more risk factors combined with a 10–20 percent risk of heart attack within the next 10 years) lower their LDL levels to under 100 mg/dL. (The previous desired level, set in 2001, was 130mg/dL or lower). 3

NCEP’s 2001 and 2004 recommendations resulted in dramatic increases in the number of people for whom statin therapy is considered appropriate. These guidelines are problematic, however, because there is simply not enough evidence to uphold their application on such a broad basis. The theory of significantly reducing LDL levels among high-risk and moderate-risk individuals may be interesting, but it has not been proven to be effective in preventing CHD. Lower LDL levels have not been proven to decrease the risk of CHD in people of all ages; the Framingham study only found a strong association between high LDL cholesterol and CHD in people up to age 60. And, LDL levels were found to increase the risk of overall death rates only through age 40.

As John Ambramson, MD and James Wright, MD write in The Lancet, “The current guidelines are based on the assumption that cardiovascular risk is a continuum and that evidence of benefit in people with occlusive vascular disease (secondary prevention) can be extrapolated to primary prevention populations.” 4 In other words, just because high LDL levels are a risk factor for CHD, it can’t be assumed that very low LDL levels are beneficial. The guidelines also attempt to apply data on people with CHD to healthy individuals generally.

It just isn’t good medicine to make such broad assumptions about the benefits of taking any drug at the potential expense of the health of millions of individuals. Further, the drops in LDL levels called for by the guidelines are so dramatic as to be difficult (if not impossible) to attain through lifestyle and diet changes, thus guaranteeing an increase in the number of people who are prescribed statins after failing to reduce LDL levels on their own. Finally, the fact that the majority of the NCEP guideline-writers have financial ties to the drug industry is extremely troubling. Eight of the nine authors of the 2004 recommendations have ties to statin manufacturers, a fact that was not originally disclosed when the guidelines were first published. These conflicts of interest among the guideline-writers severely damage the credibility of their recommendations.

Where Are the Women?

Although statins are being aggressively marketed to women, their effects on women have not been sufficiently studied. There is no solid evidence, as yet, that women benefit from taking these drugs, and women make up less than one third of these women to take the drug. But, it has never been shown that these women’s overall mortality rates decrease as a result of statin use. There is currently no indication that women of any age or any risk level will benefit from taking statins to prevent CHD and other heart conditions - yet this is precisely how statins are being marketed to women.

What About Older Adults?

Another interesting aspect is the debate over statins’ use as primary prevention in individuals over 65. The NCEP guidelines recommend lowering cholesterol levels in this age group, but the link between high cholesterol and CHD present in younger adults has not been observed in those over 65. As with women, there is not enough compelling evidence to recommend statin therapy for older adults who do not already have heart disease.

The Bottom Line

Because of the weak evidence and questionable medical guidelines, the NWHN, along with other health advocacy groups, has concluded not only that statins are over-sold, but also that their benefits have not been sufficiently proven to justify such large-scale use. The fact that the adverse effects of statins (like muscle damage) have been downplayed and are rarely published with other (more positive) results adds to the growing list of concerns about this class of drug.

Statins remain a good choice for most men with heart disease, and may be an option for some men who are at significant risk of developing CHD. But women with heart disease need better treatment than statins currently seem to offer; moreover, there is no evidence that women who are at risk of developing CHD will benefit from the therapy.

Statins need to lose their status as miracle drugs, and coronary heart disease and cholesterol need to be studied more carefully, free of assumptions about what we think we know. Heart disease remains a significant health concern, but putting millions of healthy people on statins has not yet been shown to improve overall public health or reduce mortality.

References


Elektra Kaczorowski is NWHN’s former Health Information Coordinator.
New Barriers to Emergency Contraception Access for Rape Victims: A Report from Connecticut

By Reena Singh

“If emergency contraception is available over-the-counter, can’t a hospital just send a rape victim to the pharmacy to get it? She has 72 hours to take it. It’s not an emergency.”

“What about the rights of the Catholic hospitals who believe that emergency contraception is a chemical abortion?”

“Can’t the hospital call in a rape counselor, who could have emergency contraception in her purse and take the rape victim to the ladies’ room and give it to her there?”

These were some of the uninformed and maddening questions I heard in March during a legislative hearing in Connecticut on the proposed Compassionate Care for Rape Victims bill (Senate Bill 1343), which would require hospitals to provide emergency contraception (EC) on-site to rape survivors.

All I could think was: “What about the woman?”

The needs of the woman who has just been raped had disappeared from sight in that legislative hearing room. The legislators’ questions assumed that traumatized rape survivors (who often lack their own clothing, money, or transportation) should be forced to go elsewhere for EC when they left the hospital emergency room. The legislators’ questions and suggestions also ignored the fact that obstacles still remain for women seeking EC in pharmacies.

Over-the-counter pharmacy access to EC has been an important victory for women. The Food and Drug Administration’s (FDA) decision in August 2006 to allow over-the-counter access left some barriers in place, however especially for young women, immigrant women, and women on Medicaid. Speciﬁc barriers include:

- Women under 17 years of age still need a prescription from their health care provider to obtain EC – unless they live in one of the nine states where, under special protocol or collaborative agreement, a pharmacist may prescribe and dispense EC without a prescription.
- EC purchasers must present identification, which may make it difficult for immigrant women who lack government-issued identification.
- Medicaid recipients in some states may be required to obtain a prescription for EC in order for it to be covered under the public insurance program. If EC is not covered by Medicaid, the costs ($25-$45) can be prohibitive for many.

In addition, some pharmacists and pharmacies still refuse to dispense or stock EC based on their own personal objections. EC is not kept on the shelves, but behind the pharmacy counter. Imagine going to the pharmacy following a rape and, instead of receiving EC, getting a moralistic lecture from a “pro-life” pharmacist.

The Connecticut legislators who assumed that rape survivors could “just go to the pharmacy” also did not recognize the traumatic and difficult circumstances these women face. At the hearing, a rape crisis advocate testified about her experience when she took a survivor who didn’t have any money, and who could barely speak because of her trauma, to buy EC at a pharmacy. The advocate had to file special paperwork to cover the costs of EC and then both women had to wait in the pharmacy with other customers.

The advocate explained that rape victims typically have lost their wallets and have no money at hand, and are unlikely to have a car at the hospital. Because of their assault and/or police specimen collection requirements, rape victims’ clothes are usually unavailable and the woman is likely to have to leave the hospital in a hospital gown or borrowed clothes. Requiring a woman in this condition to get to another location to get EC, even if it’s not an emergency, is an unconscionable continuation of her trauma.

Some of the Connecticut legislators discussed the feasibility of sending rape survivors to another hospital to obtain EC if she originally went to a Catholic facility that refuses to provide the medication or requires unreasonable procedures before making EC available. This is more common than one might expect. For example, Connecticut’s Bishops have imposed a protocol at the state’s Catholic hospitals requiring rape victims to take an ovulation test before they can be offered EC. Ovulation is tested by using a luteinizing hormone urine dip test (LH test); if the test is positive, the rape survivor is deemed “ineligible” for receiving EC and must be sent elsewhere. The rationale, according to a spokesman for the Connecticut Catholic conference, is that once a woman is ovulating “EC can no longer work as a contraceptive, but instead is a chemical abortion.” The concern, he explained, is that EC could interfere with the implantation of a fertilized egg.

There are three serious flaws in this rationale. First, it is extremely difﬁcult to determine exactly when a woman is ovulating, so the tests are unreliable. Asthma medications, antibiotics, alcohol and other substances can all interfere with the results of an LH test. Second, an ovulation test does not show whether a fertilized egg is present – it only shows that a woman may be ovulating, or may be about to ovulate. And, finally, there is no scientiﬁc proof that EC works by interfering with the implantation of a fertilized egg; that is just an unproven theory.

The delay involved in testing a rape victim for ovulation and then sending her elsewhere if she is deemed ineligible to receive EC at a Catholic hospital actually increases her risk of pregnancy. EC is more effective the...
**Microbicides**

**Figure 1: Microbicides in large scale effectiveness trials (Phase 2B or 3) as of March 2007**

<table>
<thead>
<tr>
<th>Product Sponsor</th>
<th>How it works</th>
<th>Number of Women Enrolled</th>
<th>Location</th>
<th>Preliminary Results Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer Gel HPTN035-NIH</td>
<td>Vaginal Defense / Acid Buffer: BufferGel works to keep the vagina acidic even in the presence of semen, and creates a physical barrier that stops or slows down the passage of pathogens into the vaginal and cervical walls.</td>
<td>3,100 women Shared trial with PRO2000</td>
<td>South Africa, Malawi, Tanzania, Zambia, Zimbabwe, and U.S. (Philadelphia)</td>
<td>April 2009</td>
</tr>
<tr>
<td>Carraguard Population Council</td>
<td>Attachment Inhibitor: Carraguard provides a physical barrier between pathogens and vulnerable cells in the cell wall (epithelium) of the vagina or rectum.</td>
<td>6,299 women</td>
<td>South Africa – 3 locations</td>
<td>December 2007</td>
</tr>
<tr>
<td>PRO2000 (.5%) HPTN035-NIH</td>
<td>Entry and fusion inhibitor: PRO 2000 binds to viruses and bacteria to prevent them from binding to, and infecting, healthy cells.</td>
<td>3,100 women Shared trial with BufferGel</td>
<td>South Africa, Malawi, Tanzania, Zambia, Zimbabwe, U.S. (Philadelphia)</td>
<td>April 2009</td>
</tr>
<tr>
<td>PRO2000 (.5 and 2%) DFID, MRC</td>
<td>Same as above.</td>
<td>9,763 women</td>
<td>South Africa, Uganda, Zambia, Tanzania</td>
<td>December 2009</td>
</tr>
</tbody>
</table>

**African Microbicide Advocacy Group**

are continuing to answer advocates' questions; facilitate dialogue and debate; and develop an advocacy agenda that prioritizes participants' rights, enhances scientific transparency, and encourages deep scientific reflection. (Learn more about this work at: [www.global-campaign.org/cellulose-sulfate.htm](http://www.global-campaign.org/cellulose-sulfate.htm)).

**Demonstrating Public Demand in the U.S. — the Microbicide Development Act**

In the wake of the CS trials’ closure, advocates, researchers and legislators are working together to ensure sufficient public funding for the continued search for a safe and effective microbicide. Since the pharmaceutical industry has not yet invested significantly in this field, microbicide research depends on governmental and philanthropic investment. Yet, right now, barely three percent of the U.S. budget for HIV/AIDS research is spent on developing microbicides.

To mark International Women’s Day on March 8, 2007, a bipartisan group of senators and representatives introduced the Microbicide Development Act (MDA) of 2007. Sponsors include Sen. Barack Obama (D-IL), Sen. Olympia Snowe (R-ME), Rep. Jan Schakowsky (D-IL), and Rep. Christopher Shays (R-CT). The Act calls for improved coordination and expanded resources for microbicide research and development activities at the National Institutes of Health, the Center for Disease Control and Prevention, the U.S. Agency for International Development, and the MDA. NWHN members can play a pivotal role by contacting your legislators to support the MDAs. A petition, sample letter, and advocacy email system are at: [http://www.global-campaign.org/legislative advocacy.htm](http://www.global-campaign.org/legislative advocacy.htm). If you call your Congress members, give them this simple message: “I am calling to ask Representative/Senator ____ to sponsor the H.R.1420/S.823 Microbicide Development Act. This bill can really make a difference in addressing the AIDS pandemic by supporting the development of important HIV prevention options that women can control.”

The real heroines and heroes are the women who enroll in these trials. Over two years, on average, trial participants each attend 29 study visits — including monthly visits for HIV and pregnancy tests – and go through 11 pelvic exams. Without their participation and commitment, it would be impossible to discover an effective microbicide. This month, take a moment to write or call your legislators to honor their commitment and move one step closer to getting a new prevention tool into women’s hands.

**References**


Bindiya Patel is special projects manager for the Global Campaign for Microbicides, and a proud board member for the National Women’s Health Network.
Hold the Hype on HPV
by Alicia M. Bell

A week before my 27th birthday, I’ve been thinking beyond my usual self-assessments and musings on the number of candles on my birthday cake. I can’t stop wondering where women my age see themselves in the context of the ongoing, frenzied debate over Gardasil, the only FDA-approved vaccine for the human papillomavirus (HPV). In addition to its marketing campaign, Merck, Gardasil’s manufacturer, aggressively pushed for legislation to require mandatory vaccination of school-aged girls. In the wake of the resulting major public outcry, Merck abandoned this tactic, but its political faux pas further complicated the murky issues surrounding HPV’s link to cervical cancer. (See the March 2007 issue of the Women’s Health Activist for Adriane Fugh-Berman’s column on the campaign.)

The HPV discussion currently focuses largely on young, school-aged girls—because Merck’s controversial push for mandatory vaccination in this population caused a general knee-jerk, parental freak-out. Many parents are probably uncomfortable with the HPV vaccine because it makes them think of their children one day having sex, which they almost certainly will (an issue they don’t have to consider with other childhood vaccinations!) Eventually, the dust will settle and public health authorities will promote a stronger, more cohesive and (I hope) less biased public message on the HPV vaccine. But, in the meantime, where does this leave women who are past the age of school vaccinations? Women over 18, like me, must decide whether to get vaccinated on our own.

Gardasil has been approved for use in females between the ages of 9 and 26, so there are many young adult women who will have to deal with pressure to get the vaccine. Doctors are allowed to prescribe a therapy for any purpose in any population after its approval by the Food and Drug Administration (FDA), so it’s possible that doctors will advise women over 26 to receive the vaccination. It is also possible that women over 26 may demand vaccination because, “Hey, it can’t hurt.” One’s level of sexual activity is, however, the important determinant in whether to get vaccinated. The HPV vaccine makes the most sense for women who have never had sex or had very few sex partners. Although Gardasil isn’t approved for use in men, men are most often the carriers who infect their female partners. If the vaccine is shown to be effective in men, then vaccinating males might be good for women, too. Currently, there are lots of questions about the choices that can be made to prevent cervical cancer—questions that are unlikely to be answered in the politically charged climate.

I first heard about HPV several years ago while in college, where I learned that it is sexually transmitted, that people may not have symptoms when infected, and that it causes the majority of cervical cancers. At least 80 percent of women will have had an HPV infection by the time they are 50. At first, I was angry. You always hear about HIV, gonorrhea, syphilis, and herpes—so why hadn’t I heard about this virus before? Then I saw a television episode of “Law and Order: Special Victims Unit,” in which a woman who had been sexually assaulted was diagnosed with HPV. The fictional detectives wanted to find the young woman quickly so that she could get treated for the infection immediately, since HPV can cause cancer. Although this was just a TV show, I wondered about this: was HPV an emergency? What treatment could the woman get? I thought there was no treatment for HPV!

I learned about treating HPV firsthand some time later. One year ago, a doctor nonchalantly informed me that I had genital warts caused by HPV, and that I could treat them with a cream or she could burn the warts off. It really bothered me that she acted like it was no big deal, and I was a bit taken aback because I worried that my chances of getting cervical cancer later in life had automatically increased with the HPV infection. My next emotional reaction was guilt that I had been sexually irresponsible. I wondered if I should tell my past partners that I had HPV. I worried about how long I had been infected. I felt really confused; was HPV something I should stay up nights worrying about, or was it as normal a part of women’s life as yeast infections?

It turns out that HPV is quite common—so common that a gynecologist told me women could think of it as normal flora. HPV infection often goes unrecognized because there may be no symptoms, but it can be diagnosed through an abnormal Pap test or from the presence of genital warts. The genital warts caused by certain types of HPV (including types 6 and 11) can be removed with gels, creams, cryotherapy (literally burning them off), or surgery, but there is no cure for HPV. Fortunately, this is generally not a problem because the infection almost always goes away on its own: 90 percent of women with cervical HPV infection have no detectable virus within two years. Additionally, the types of HPV that cause genital warts are not the same types that can lead to cervical cancer. Therefore, HPV is only a cancer risk for women who have persistent infection with high-risk HPV, such as types 16 and 18.

After I learned that HPV is very common, that most people clear the virus, and that genital warts are not caused by the type of HPV associated with cervical cancer, I was no longer worried. Condom use dramatically reduces the risk for HPV infection, but it is not fully protective; HPV can be transmitted through skin that isn’t covered by a condom (such as the vulva, scrotum, or perianal region). Wow— I wish I had known this before the doctor told me that I had HPV.

Considering all this, should sexually active young women run out and get the HPV vaccine? Maybe not. The vaccine is not very effective in those who have
already been exposed to one of the types of HPV it targets. If you have never had sex (or had very few sex partners), you may benefit from the vaccine. If you have had multiple sex partners, you are unlikely to benefit from the vaccine because your level of sexual activity is a more important determinant than age for getting HPV. Also, HPV exposure usually occurs within the first few years after a person becomes sexually active — that’s why it’s recommended that women get the vaccine before having sex (or very soon thereafter). Nearly one-quarter of U.S. teens have had sex by age 15, and 70 percent have had sex by the time they are 18 — that’s why vaccination at a much younger age is the most effective public health intervention.3

A general sense of dread surrounds HPV and cervical cancer, and I think most women are relieved there is a vaccine. But I worry that the public is getting an oversimplified view of HPV and its relation to cervical cancer. From a public health perspective, it makes sense to vaccinate all girls before they’ve had sex. But for women who have had sex, the number of sexual partners — not age — should be the most important factor in the decision to get vaccinated. I fear that many women will be subjected to unnecessary vaccinations, or stop seeking regular cervical cancer screening. It is possible that confusion surrounding the vaccine could lead to a misuse of resources and could become a barrier to achieving the best possible health outcomes for women.

Cervical cancer screening through regular Pap tests is still crucial, especially since the currently available HPV vaccine does not protect against all types of high-risk HPV strains. The Pap test has truly been the first line of defense against developing cervical cancer and U.S. screening programs have greatly reduced deaths from cervical cancer in this country. The single most important factor associated with developing invasive cervical cancer is never (or rarely) getting screened.4 The American Cancer Society estimates that in 2007, 11,150 women will develop invasive cervical cancer in the U.S. and 3,670 will die.5 Even in the U.S., most of the women who die of cervical cancer never had regular Pap tests.1

The World Health Organization (WHO) estimates that there are 250,000 annual cervical cancer deaths worldwide, making it the second most common cause of female cancer deaths.5 The vast majority of these deaths are in countries where women do not have access to regular screening, and the HPV vaccine has amazing potential to save many lives in these countries. Despite the hype surrounding HPV, regular Pap tests and condom use are still key to reducing risk for genital HPV infection and the HPV-associated problems of genital warts and cervical cancer — even if you do decide to get the HPV vaccine. -

For references, see page 13.

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If the non-Catholic hospital 10 minutes away will provide EC when a woman “fails” a meaningless ovulation test. It does not matter that EC can be used up to 72 hours after intercourse. Rape survivors have the right to receive all aspects of the care that they need in what is probably the worst moment of their lives. What should matter to legislators considering bills such as this one are the needs of the woman.

At press time, the bill had passed out of committee and is waiting for a vote. For more information on the bill, see: http://www.connsacs.org/CompassionateCareforRapeVictims.htm.

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**Tribute Gifts to NWHN: A Thoughtful Way to Commemorate Someone Special**

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**HOST A NETWORKING EVENT FOR THE NETWORK!**

Have fun introducing your friends and colleagues to the Network!

Malika Redmond hosted a successful networking event and fundraiser for more than 30 people in Atlanta on March 16th. The event was held at the newly opened women-owned Mindspace Tea Bar and Lounge, a comfortable venue with many tea specialities. Malika is a NWHN Board member who lives in Atlanta, Georgia. Her friends, family and colleagues from local community organizations came and mingled with NWHN members and the Board of Directors. Several joined the National Women’s Health Network as new members. Malika spoke about the NWHN’s work and guests were also treated to remarks from both Cindy Pearson and featured speaker Dazon Dixon Diallo, founder of SisterLove. Dazon shared her experience as the founder of a feminist, grassroots HIV/AIDS project and the lessons she’s learned from SisterLove’s work with women world-wide.

You don’t have to be a Board member to host an event. Get in touch with Jill Battalen, Director of Individual Giving, at 202.347.1140 to find out more about hosting a community network event.
In all likelihood, every time you fill a prescription, information about you is sold to a company that then resells that information to pharmaceutical companies for promotional purposes. Pharmaceutical companies may know that you used Seasonale for six months last year, then switched to a generic birth control pill; that you took the antibiotic Zithromax in September and Ketec in December; that you use a nasal steroid during the spring pollen season every year; and that you filled one prescription for Prozac last month but haven’t picked up a refill.

Feeling invaded yet? Your name is removed from your medication history, which is supposed to make it all better. Industry may know all your intimate health details, but as long as they know you as “Number 0178” rather than by your name, it’s all legal.

“Prescription tracking” is the system by which pharmaceutical companies determine the success or failure of all promotional efforts. IMS Health, the largest information distribution (or data-mining) company, obtains records on more than two thirds of prescriptions filled in community pharmacies. Other information distribution companies include Dendrite, Verispan, and Wolters Klower.

In many cases, drugs used by a patient reveal his or her diagnosis. Insulin, for example, is only used by diabetics; protease inhibitors are only used by those living with HIV; and antihypertensives are primarily used by people with high blood pressure. In other cases, drugs may be used for multiple purposes. Some medications, for example, are used for both seizures and migraines. Antibiotics, of course, are used for infection, but generally one can’t tell which infection someone has by the antibiotic being taken. So information purchased from pharmacies may be supplemented with information purchased from insurers to pinpoint individual patients’ diagnoses.

Gathering prescription information on specific patients is a recent marketing development that is being used to refine information on physicians’ prescribing preferences. The identity of individual patients is of little importance to pharmaceutical companies. What they are really after is information about a specific physician’s prescription-writing habits.

Physicians’ names are not protected by privacy laws in the way that patient names are protected — and data-mining companies have long gathered information on the number of prescriptions a particular doctor writes for specific drugs. Although pharmacies keep data on physicians that are identified only by the physician’s number, these numbers are easily matched to physician names by comparing them with lists of names purchased from the American Medical Association (AMA) Physician’s Masterfile. The Physicians’ Masterfile is a database of the demographic information on all U.S. physicians, whether or not they are members of the AMA. Licensing information from the Physician’s Masterfile, and other database product sales, netted more than $44 million for the AMA in 2005.

Physicians control the distribution of prescription drugs, so every bit of information on them is valuable to the pharmaceutical industry. (Although physician assistants and nurse practitioners prescribe as well, both of these groups tend to prescribe more rationally than physicians. Because physician assistants and nurse practitioners do not prescribe large amounts of expensive branded drugs, their prescribing habits are not usually tracked. That may change in the future). The industry uses this prescribing data to evaluate the efficiency of “detailing”, their term for the promotion of drugs to doctors by pharmaceutical sales representatives (otherwise known as drug reps).

Prescribing data are used to rank physicians on a scale from one to ten based on how many prescriptions they write. Drug reps also use prescribing data to track how many of a physician’s patients receive specific drugs, how many prescriptions the physician writes for targeted and competing drugs, and how a physician’s prescriptions change over time. All this information helps drug reps tailor their marketing messages to the physicians.

New Hampshire was the first state to ban the sale of prescription data; it was promptly sued by IMS and Verispan. Other states considering similar bills include NY, N E, AZ, IL, KS, M E, M A, R I, T X, V T, W A, and W V. Data-mining companies argue that prescription data is used for public health purposes, but the use of these data by government and academic researchers is vanishingly small.

Make no mistake about it: the purpose of prescribing data is to assist industry to influence physicians to prescribe the most expensive drugs.

What can you do about this? Support legislation banning the sale of prescribing data and medical histories, and encourage your state legislators to introduce such legislation if they haven’t already. In the meantime, ask your pharmacy — and your insurance company — if they sell prescribing or medical history data. Most chain pharmacies do, while independent pharmacies are less likely to sell these data. If your pharmacy or your insurance company sells your data, let them know you don’t appreciate it and that (if there is a pharmacy or insurer in your area that doesn’t sell your information) you’ll be switching your business. Using pharmacies and insurance companies that opt out of the data mining system is a good way to support companies that protect your privacy, and to alert these businesses that selling your medical history, even with your real name removed, for pharmaceutical companies to use for drug promotion is not acceptable.

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A new federal rule intended to prevent illegal immigrants from receiving Medicaid requires U.S. citizens to provide “satisfactory documentary evidence of citizenship” (through a passport, or a driver’s license with birth certificate). This policy has adverse affected American citizens. State officials have seen a steady decline in Medicaid enrollment and believe it is due to the new federal policy. Declines have been seen in Florida, Iowa, Kansas, Louisiana, New Mexico, and Ohio.

South Carolina is poised to mandate that women seeking an abortion must view ultrasound images of the fetuses before the procedure. A 1994 law already requires SC clinics to inform women about fetal development and abortion alternatives and forces them to delay the procedure for an hour after receiving the information. While a few House Democrats are fighting the legislation, many feel pressured by their constituency to approve the compulsory ultrasounds. If passed, South Carolina would be the only state with this requirement.

In March the Court of Appeals ruled that the Union Pacific Railroad Company did not discriminate against female employees by excluding contraception from its health insurance coverage. The ruling directly counters a 2000 decision by the Equal Employment Opportunity Commission that the Pregnancy Discrimination Act requires employers to cover women’s contraception if they cover drugs and devices for other conditions. The Court asserted that the Act could not have been violated, because contraception is “not related” to pregnancy. The ruling could encourage other employers to cut costs by refusing to offer contraception coverage, affecting the lives of millions of women who rely on employer health plans to cover contraception.

After threatening to reduce the Office of Women’s Health’s (OWH) budget by 25%, the Food and Drug Administration (FDA) has backed down due to widespread public outcry and will maintain level funding of OWH. Leaks about the FDA’s planned cuts surprised women’s health activists and members of Congress, who had passed level OWH funding at $4 million. OWH redresses inequities in research, health care services, and education that place women’s health at risk.

April was Sexual Assault Awareness Month and events were held nationwide to raise awareness about sexual violence and assault. The annual event is a result of decades of efforts by women’s activists to highlight sexual violence as a major social issue. The movement now raises awareness about abuse among commercial sex workers; men; minorities; and within the gay, lesbian, bisexual, transgender and questioning community. Compassion, education, and empowerment for all? Now, that’s something to celebrate.

Ohio is poised to become the eighth state to reject federal abstinence-only-until-marriage funds, following the lead of others including California, Connecticut, Maine, Montana, New Jersey, Rhode Island and Wisconsin. Governor Strickland (D) announced that he would phase out the grants, citing the lack of evidence for these programs’ effectiveness, and calling them an “unwise use of tax dollars.” The Sexuality Information and Education Council of the United States (SIECUS) attributes this shift to the new Congressional leadership and predicts that more states will follow suit, eventually influencing a beneficial policy change for more effective programs.

Inside: Exploring Statins: What Does the Evidence Say?
Young Feminist: Hold the Hype on HPV

References:


