

Conference Report
October 2003

The Unfinished Revolution

In Contraception

*Convenience,
Consumer Access
And Choice*

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This is a report from the meeting **The Unfinished Revolution in Contraception: Convenience, Consumer Access and Choice**, convened on October 16, 2003, by the Reproductive Health Technologies Project and The Alan Guttmacher Institute.

Kirsten Moore, Lawrence Finer and Jacqueline Darroch served as meeting organizers and editors of the report. Jacqueline Koenig prepared notes of the meeting as well as initial drafts of this report. Rose MacLean copyedited the final draft of the report. Christine De Mars was the graphic designer. We would also like to thank Amy Allina, Heather Boonstra, Sharon Camp, Linda Dominguez, Beth Fredrick, Kate Miller, Kate Schaffer, Karen Shea, Susheela Singh, Debbie Wilkerson and Alea Woodlee for taking time to review earlier drafts of the report.

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A companion slide presentation, "Contraception in the United States: Current Use and Continuing Challenges," was prepared for the meeting. The presentation is available on The Alan Guttmacher Institute's Web site at <http://www.guttmacher.org/presentations/contraception-us.html>.

On October 16, 2003, the Reproductive Health Technologies Project and The Alan Guttmacher Institute hosted a meeting entitled “The Unfinished Revolution in Contraception: Convenience, Consumer Access and Choice.” The idea for the meeting sprang from an interesting marketing anecdote about the Ortho Evra patch, manufactured by Ortho-McNeil and approved by the U.S. Food and Drug Administration (FDA) in 2001. Ortho-McNeil advertised the patch in women’s magazines. The Ortho Evra ads included a peel-off demonstration patch to give women a sense of what the patch feels like. Soon after magazines hit the stands, a handful of women who did not understand that the demonstration patch was inert called the manufacturer and asked where they could get more magazines. The story affirmed what we already know—that industry ads are insufficient education tools. But more importantly, it raised the question: Why isn’t it simpler for women and men to access contraception in the U.S.? Why isn’t it as easy as picking up contraception in a magazine?

More than 40 years after the contraceptive revolution began with the approval of the contraceptive pill, the United States lags far behind its social and economic counterparts when it comes to effectively reducing the burdens of unintended pregnancy and of sexually transmitted infections (STIs) and related fertility problems. Despite the surge of contraceptive products approved by the FDA in recent years, more can and should be done to help close the gap between Americans’ reproductive health needs and the information, technology and services currently available to them.*

The October 2003 meeting brought together a diverse group of interested parties, including reproductive health care providers, advocates, social scientists, product manufacturers, policymakers and donors. Participants brainstormed, shared new information related to the field and worked toward the establishment of a broad platform from which to advocate policy and education initiatives to make contraceptive methods more convenient and effective for women and their partners. The session focused on supply-side factors—the impact that manufacturers, providers, educators and advocates could have—rather than actions that women and men could take to improve use and effectiveness.

* A presentation summarizing U.S. contraceptive use was prepared in advance of the meeting. A revised version of that presentation, “Contraceptive Use in the United States: Current Use and Continuing Challenges,” is available on The Alan Guttmacher Institute’s Web site at <<http://www.guttmacher.org/presentations/contraception-us.html>>.

One central theme that ran through much of the discussion was the extent to which contraceptive services should remain linked to a medical model. To help legitimize contraception in the eyes of policymakers and the general public, advocates in earlier years argued that contraception was a medical service; health care professionals were needed to screen prospective users and prescribe methods. The primary goal of family planning visits became “matching the woman to a method” based on her medical history and her desire to postpone pregnancy for the short or long term or to end her fertility.

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As the real-world experience of contraceptive use continues to grow over time, some health care professionals argue that today’s contraceptive options are so safe and straightforward that women do not need extra services to use them correctly. Others acknowledge that although most contraceptive methods are safe for most women, successful contraceptive choices reflect lifestyle and preferences, and effective counseling can help women choose methods that fit closely with their lifestyle, relationship status and childbearing expectations. It is not difficult for women to start a contraceptive method; the challenge comes in sustaining successful use, particularly as the circumstances of their lives change. Therefore, the priority is on developing services in addition to the methods themselves.

There was spirited debate about how to build on recent successes in the field (e.g., creating such “desirable” side effects for contraceptives as the acne indication for Ortho Tri-Cyclen or enacting laws that require prescription drug insurance programs to cover contraceptives). Still, many meeting participants—even those with extensive marketing expertise—acknowledged that when it comes to meeting consumers’ needs, they have more questions than answers about what exactly consumers want.

Therefore, a second significant theme of the meeting was that more consumer research is needed across the board, including pre-contraceptive development focus groups that vary by age, race, geographic location and fertility status to determine what women and men think is missing from the current armamentarium; segmented audience research prior to public education campaigns; and more

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evaluative research so that successful models can be replicated and failed strategies are not repeated. Moreover, participants focused on turning the results of consumer research into items that can be acted upon and on coming up with new and better ways to reach women and men.

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The discussion highlighted opportunities for action and pointed to gaps in our knowledge of the factors that drive consumer behavior when it comes to reproductive health. This report is a synthesis of the wide-ranging discussion at the meeting and includes information from external sources where relevant. It is not intended to be an exhaustive exploration of issues surrounding contraceptive use, but rather is aimed at stimulating further attention and action.

Topics covered in this report include:

- New Models for Service Delivery
 - > De-linking Contraceptive Care from Provider-Based Primary Care and Other Reproductive Health Care
 - > Over-the-Counter Access
 - > Expanding Prescriber Authority
 - > Advance Prescription, “Smart Start” and “Quick Start,” and Easier Refills
 - > Expanding Support Staff Training and Ongoing Patient Communication
- Gaps in Public and Private Insurance
- New Products, Regimens and Packaging
- Outreach Efforts: Knowing Your Audience
 - > Advertising
 - > Social Marketing
 - > Providers
 - > Print Media
 - > Internet
- Action Steps

A meeting agenda and list of participants appear in Appendices A and B.

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New Models for Service Delivery

What kinds of services are necessary to give women the confidence that the methods they are currently using are the right methods for them? In recent years, several pilot service delivery models have demonstrated success and, if scaled up, may have a national impact on reproductive health delivery systems. Emergency contraception has served as a test case for many of these changes, including advance prescription and pharmacy access; ideally, it will play a similar role in evaluating the effectiveness of switching methods to over-the-counter (OTC) status.¹ Other models being tested and implemented include “quick start” (i.e., starting women on a hormonal method the day they come into the office regardless of the cycle day) and the elimination of pelvic exams as a prerequisite to an initial prescription for hormonal contraception. This process of responding to consumers’ interests can and should go further still.

A note of caution, however, as we move forward: While “demedicalizing” contraceptive services may make them more convenient for some women, care must be taken so that other women—including poor women and first-time contraceptive users—are not left behind. If the goal is to expand access through programmatic innovations, the focus must be on providing individuals or populations with links to contraception that they might not otherwise have, without eliminating access to services that currently exist.

De-linking Contraceptive Care From Provider-Based Primary Care And Other Reproductive Health Care

Traditionally, pelvic exams have been required in order to obtain hormonal contraception in the United States. However, research has shown that these medical exams, although important to women’s health, are not medically necessary to assess whether women are appropriate candidates for hormonal contraception.² In fact, most countries do not link pelvic exams to receipt of hormonal contraception.

Everyone agrees that women should have such basic health care services as high blood pressure screening and cervical cancer screening. However, the debate continues as to whether using contraceptive care as a bridge to those services is appropriate or is overly paternalistic, creating unnecessary barriers to access that can increase women’s risk of unintended or unwanted pregnancy.

Some clinics are testing the theory that de-linking contraceptive care from other services will lead to increased access. In 1998, Planned Parenthood Federation of

America (PPFA) changed its medical protocol requirements for affiliates and eliminated the pelvic exam requirement. PPFA is currently studying the effectiveness of the new protocol by assessing how many affiliates have adopted it and whether access has increased.

Another idea being tested is offering Web-based prescriptions for certain hormonal methods (the pill, the patch and the ring). In Oregon, Planned Parenthood of the Columbia/Willamette recently began offering women a prescription for a 60-day supply of hormonal contraceptives via the Internet.³ Women fill out an online health assessment and a nurse practitioner follows up by phone. Once a prescription has been approved, women can receive pills, patches or rings through overnight mail, at a pharmacy or at a Planned Parenthood clinic.

Questions remain as to the impact that separating contraception from other medical services may have on women’s overall reproductive health status. Although any family planning client could request and receive cervical and STI screening, for example, it is unclear whether women will seek these services if contraception and basic health care are de-linked. Similarly, will community-based organizations that lack sufficient resources be able to fill the STI information gap if women are not receiving this information from family planning clinics? Researchers need to consider whether these kinds of questions are testable hypotheses. Pilot projects can help evaluate potential negative or unintended consequences and help identify appropriate solutions.

Over-the-Counter Access

One mechanism to improve women’s access to contraceptives is to make more methods available without a prescription; but which methods, if any, are appropriate for an OTC switch? If safety were the sole criterion, some of the top candidates would be cervical barriers and the minipill. However, the markets for these methods are small. Ibis Reproductive Health, Family Health International and the Harvard Center for Population and Development Studies organized a meeting in March 2004 on how to take oral contraceptives over the counter. They concluded that because of the limited market for the minipill, makers of progestin-only pills should not pursue an OTC switch, and additional research is needed before OTC status is sought for combined oral contraceptives. Although there is a lack of consensus, it is worth noting that a handful of experts contend that most contraceptive options—with the exception of the IUD—are appropriate candidates for a switch.⁴

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What information do women need to assess the risks and benefits associated with using a particular method? Are they able to use a product without the supervision of a health care provider? Can product instructions be simplified so they can be understood by a vast majority of prospective users? Do teenagers have enough basic information to follow product instructions? Some women may find that a visit with a health care provider gives them greater confidence in their method selection or their ability to manage side effects appropriately.

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Finally, it is important to consider whether OTC status actually leads to increased access and if so, then for whom? Condoms, for example, are now OTC, but because of problems with theft, they are sometimes placed in a locked display case behind the cashier's counter. Does this deter purchase or use by young people? If prescription contraceptives were switched to OTC status, would Medicaid and other insurance programs continue to pay for them? What needs to be done to ensure that they do? Can and will the contraceptive industry help resolve issues of pricing and reimbursement? Further study on these and related questions could help build a stronger consensus within the health care and advocacy communities on whether OTC availability is desirable.

Expanding Prescriber Authority

Giving pharmacists the authority to prescribe contraceptives is another strategy for increasing contraceptive access. Direct access to emergency contraceptives through pharmacists has proven that contraceptives can be prescribed outside a clinical setting and has led to expanded access for at least some women.⁵ The model has been so successful that a new pilot program, the Direct Access study, is underway in the state of Washington to assess the feasibility of pharmacists' providing other forms of contraception, including the pill, patch and ring, at community pharmacies.⁶ Data collection is anticipated to be complete by the end of 2005.⁷

Although the pharmacy access model is growing (five states currently have programs up and running and several

more have recently passed or are considering legislation to do the same), the model has its own set of challenges: Pharmacists want to be reimbursed for counseling; turf battles among medical groups are common; and women who cannot afford this service must still visit a clinic in order to receive free or sliding-scale contraceptives.

Nevertheless, a recent national survey of women aged 18–44 who are at risk of unintended pregnancy (i.e., are sexually active and not pregnant, postpartum or trying to get pregnant) found that 63% of respondents agreed that pills, patches and rings should be available without a prescription if pharmacists screen women first to determine if it is medically safe for them to use the method. The proportion of women who supported pharmacy access declined to 43% when screening by pharmacists was not mentioned. According to the study, an estimated 17–22 million U.S. women aged 18–44 would be likely to use pharmacy access to obtain hormonal birth control, including emergency contraceptives, if these methods were made available without a prescription. Women cited a range of advantages to pharmacy access, first and foremost the convenience of location and hours (84%).⁸

Another option is expanding the direct access model to include other providers, such as advanced practice clinicians, other mid-level health professionals or even trained lay educators. Community-based distribution programs are very common and successful in the developing world, where access to health care is otherwise limited.

Advance Prescription, “Smart Start” And “Quick Start,” and Easier Refills

Increasingly, such professional associations as the American College of Obstetricians and Gynecologists and the National Association of Nurse Practitioners in Women's Health are recommending that health care professionals provide women with a prescription for emergency contraception as part of their annual visit, thus eliminating at least one step in the race against a 72-hour clock. A recent survey from California indicated that this practice has begun to meet with some success: Six percent of emergency contraceptive users had obtained the method in advance.⁹ Moreover, 65% of the women indicated that they would be more likely to use emergency contraception if they already had it on hand, a finding that suggests a link between advance provision and increased use. Clearly, more providers should be incorporating this step into their practice.

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Several ways of making oral contraceptives and other hormonal methods more accessible and easier to remember to take are being discussed, including the development of a “smart start” pill pack that would come with a daily e-mail or voicemail reminder to take the pill.¹⁰ Another idea that is already being studied is a new way of providing hormonal methods to women called “quick start.” Traditionally, women are told to wait to start using oral contraceptives, injectables, patches or rings until the onset of menses. This directive may be difficult to follow or remember. The “quick start” approach involves having women start on their hormonal method while still at the provider’s office, regardless of cycle day.

At least two studies have been published on the use of “quick start” for oral contraceptives and have found that women who had started taking the pill during their visit to the provider were more likely to continue to their second month of use than those who had waited until the onset of menses, and that bleeding patterns did not differ significantly between the two groups.¹¹ The use of “quick start” is also being studied for other methods, such as the ring and the injectable.

Making refills more convenient can also improve the continuity of birth control use. Because of their convenient business hours and locations, pharmacies are arguably the most accessible of all health care service points. Increasingly, pharmacists are routinely providing injections, and many schools of pharmacy now require that graduates be trained to administer injections. These changes are starting to make pharmacies a viable option for the “resupply” of injectable contraceptives in much the same way as they supply refills to oral contraceptive users. In California, Pharmacy Access Partnership, a center of the Public Health Institute, developed a program called Health Step (www.healthstep.org), which partners physicians with local pharmacists to provide Depo-Provera users the choice of obtaining reinjection at their regular provider or at a participating pharmacy.

Finally, a nationally representative study of women’s oral contraceptive purchases found that 73% of women had obtained only one pack of oral contraceptives per purchase, in most cases due to health plan restrictions.¹² Such unnecessary barriers may well lead to gaps in contraceptive use and elevated rates of unintended pregnancy. If these detrimental effects were demonstrated through research, pressure could be successfully applied to policymakers and insurance companies to change restrictive practices.

Expanding Support Staff Training And Ongoing Patient Communication

Given the pressure on clinicians to do more for less money and in less time and the simultaneous goal of expanding access, prescribers need to find ways of ensuring that patients get the information and support they need for successful contraceptive use. Studies of oral contraceptive and injectable users have indicated that acceptability and proper pill use are tied in part to how well women understand the method’s side effects and noncontraceptive benefits, and to whether or not they had a positive experience with their provider.¹³

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Contraceptive users need to understand the basics of the menstrual cycle, the potential side effects associated with contraceptive use, the impact of these side effects on the menstrual cycle, and how to cope with them, particularly during the first few months of use.¹⁴ One idea suggested to address the issue is to train support staff (i.e., receptionists, registered nurses, licensed practical nurses and medical assistants) in offices and clinics to act as educators and problem-solvers for patients. These staff members are often the ones who answer the phone when a patient calls with a question. Typically, they write down the problem and have a prescriber get back to the patient with an answer. A new approach would be to have the support staff assess the patient’s problem, provide basic information over the phone and then direct the patient to specific Web sites or product hotlines for more information.¹⁵

This approach is supported in a recent guide on individualized contraceptive care published by the Association of Reproductive Health Professionals.¹⁶ The guide suggests following up with women who have initiated hormonal methods of contraception by telephone, e-mail and postcards, and also recommends training nurses and medical assistants to handle basic questions.

There are many local, state and national contraceptive information hotlines to which providers can direct patients for ongoing information and support. One hotline,

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recently launched for Depo-Provera, is sponsored by its maker, Pfizer, and staffed around the clock by registered nurses. The Depo-Provera phone line offers free counseling to new and current users who are referred by their clinicians.¹⁷ While the staff will answer all questions posed by callers, they are also prepared to offer advice tailored to the length of time the caller has been using the shot. For example, with first-time users, counselors will discuss the potential for spotting or bleeding between cycles; with women who have had their third injection, counselors will discuss the possibility of amenorrhea. An evaluation of a similar program in Canada suggests that the service has a positive impact on method continuation and user satisfaction.

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Gaps in Public and Private Insurance

Such publicly funded programs as Medicaid, Title X and school-based sex education—which are critical links in the reproductive health chain—are under attack from social conservatives. As a result, inflation-adjusted funding for Title X services has decreased by 58% since 1980.¹⁸ This has had a direct impact on the range of contraceptive options offered to women. Although federally funded clinics have to offer a mix of methods to clients, they are not required to offer every FDA-approved method and many do not have adequate funding to do so.

In the absence of deeply discounted public-sector pricing by pharmaceutical companies, many new methods—including the Mirena intrauterine system, Ortho Evra patch and NuvaRing—are not available or are available to a limited number of clients. This limitation of contraceptive options decreases the likelihood that women will find the best method for their given circumstances, and research has shown that if women do not get their first choice in a contraceptive method, dissatisfaction and discontinuation rates increase.¹⁹

In addition to the stagnation of federal funding, regulatory issues constrain services. For example, Title X, which provides free or low-cost family planning care to many low-income women in the United States, requires women to obtain a pelvic exam 3–6 months after they have obtained hormonal contraceptives.²⁰ In order to obtain products for free or at sliding-scale prices, women must get the products from a Title X clinic, even if it would be easier to go to a local pharmacy.²¹

Although contraceptive coverage in private insurance plans has improved in recent years,²² many women still lack coverage, have plans that do not cover the specific contraceptive they would like or face a prohibitive copay for their method of choice. As of April 2004, only 20 states had comprehensive contraceptive coverage mandates applying to all insurers that cover prescription drugs and devices; some of these states allow employers not to purchase plans that cover contraceptives if it would violate their religious beliefs.²³ Moreover, employer self-insurance plans are generally not covered by these mandates.

The merger of religious and secular health care institutions also continues to erode women's access to comprehensive reproductive health care. The MergerWatch project (www.mergerwatch.org) continues to document, among other examples, cases in which women have been denied tubal ligation at the time of childbirth and in which women who have been sexually assaulted

have been denied emergency contraceptives at hospital emergency rooms.

The courts continue to be a critical tool in the fight for reproductive rights. A recent case, *Catholic Charities of Sacramento, Inc. v. Superior Court of Sacramento County*, tested the constitutionality of California's Women's Contraceptive Equity Act, a law which requires employers to provide health insurance plans that cover contraceptives but exempts religious employers. The California Supreme Court ruled that Catholic Charities is not a religious employer because it offers such secular services as counseling, low-income housing and immigration services to people of all faiths, without directly preaching Catholic values.²⁴

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In addition, an analysis of data from the 1996 Medical Expenditure Panel Survey showed that 46% of women had paid \$15 or more on average per pack of oral contraceptives, and women were significantly more likely to have paid that much if they lacked prescription drug coverage, were uninsured or were privately insured but not in a managed care plan.²⁵ Ninety-three percent of women who had paid \$15 or more per pack had obtained only one pack. The authors concluded that out-of-pocket expenses and dispensing restrictions may be barriers to consistent use of oral contraceptives.

Although there are periodic national surveys on employer-based coverage of contraceptives, specific information on how methods are covered—in terms of both cost and prescription limitations—would shed light on the nuances of contraceptive coverage and barriers to access. Several participants at the October 2004 meeting thought there might be potential in harnessing consumer purchasing power as a mechanism for influencing the scope and quality of contraceptive coverage in insurance plans.

New Products, Regimens and Packaging

Since 1998, the FDA has approved at least 14 new contraceptive products.^{†26} Although the gap is closing, women in the United States still lag behind their European counterparts when it comes to contraceptive options, and U.S. women are certainly still looking for new methods. A 2001 national survey of women found that participants generally desired new options that would be easy to use and could help simplify their lives. Although a majority of the women were very satisfied with their method (56%), 75% said there is a need for methods that are more adaptable to their lives, and 90% of obstetrician-gynecologists agreed that many women need a better match.²⁷

The search for new, even more effective contraceptive products continues in both the private and the public sectors. Discussions at a symposium hosted by the Institute of Medicine on July 15, 2003, suggested that many “big pharma” companies—the traditional engines of drug product research and development—believe that the future of contraceptive technologies lies in genomics (i.e., targeting a specific genomic sequence in either men or women to maximize pregnancy prevention and limit any side effects). Although product developers are optimistic about these technologies’ potential, lack of adequate funding and industry incentives remain major impediments.

Some major pharmaceutical companies are experimenting with “dual benefit” contraceptives, an effort sparked in large part by the success of Ortho Tri-Cyclen, the first oral contraceptive to be approved for use in treating acne. In December 2003, the FDA’s Reproductive Health Advisory Committee overwhelmingly recommended the concept of a combined oral contraceptive and folic acid product put forward by Ortho-McNeil.²⁸ Other potentially desirable combinations range from contraceptives that induce weight loss to contraceptives that promote hair growth for men. Among other new delivery mechanisms, the development of a medicated tampon has been suggested.²⁹

While it is generally thought that such innovations will have a limited impact on overall contraceptive use patterns, they will give current users more opportunities to switch methods and, given the direct-to-consumer advertising that often accompanies such innovations, may encourage women to seek contraceptive services for the first time by sparking their interest in a particular product.

One of the most obvious and critical dual method needs is for pregnancy and disease prevention, an area in which research is of potential interest to industry but is still largely fueled by public-sector dollars. While the search for a viable microbicide continues, some research is also underway to test whether currently available female barrier methods protect women from STIs as well as pregnancy.³⁰ In addition, researchers are investigating the possibility of a one-size-fits-all diaphragm and a disposable diaphragm.³¹

Meeting participants also discussed ways to improve the packaging of existing methods. For example, dual packaging of oral contraceptives (including emergency contraceptives) and condoms or of oral contraceptives and emergency contraceptives may be well received by clients. On a related front, research has shown that vasectomies are not effective during the first month after surgery, so the initial method is actually a combination of vasectomy and the condom.

Another area for improvement is the content of product labels, which help to shape if not dictate clinical practice. In general, product labels are written in a complicated style to ensure liability protection and therefore do not always convey clear, practical information that consumers can readily understand. More can and should be done to ensure that information provided on product labels can be understood by a broad cross-section of the public, including women and men with low verbal or quantitative skill.

The content of labels is regulated by the FDA, which establishes class labeling for newly approved methods based on the sponsor’s clinical trials. Could more flexibility be built into the system to incorporate new information on a more consistent and timely basis? Could the FDA mandate label comprehension standards for prescription products as it does for OTC products?

The FDA has been working on a simple and uniform instructional label for all oral contraceptives; the most recent draft was released for public comment in March 2004.³² Some advocates are concerned that the proposed labeling overemphasizes some of the health risks associated with hormonal contraception and underplays some of the benefits. In addition, the proposed labeling is out of step with current clinical practice (as well as with earlier drafts) because it states that an annual pelvic exam is required for women to get a prescription and does not allow for alternative start dates. Many health professionals and advocates have submitted comments, and a revised version is pending.

† Cycllessa (2004), FemCap (2003), Lea’s Shield (2002), Lunelle (2000), Mirena (2000), NuvaRing (2001), Ortho-Evra (2001), Plan B (1999), Preven (1998), Seasonale (2003), Tri-Cyclen Lo (2002), Essure (2002), VasClip (2002) and Yasmin (2001).

Outreach Efforts: Knowing Your Audience

The importance of knowing one's audience prior to communicating with them about contraception is critical to the success of one's message, whatever that message may be. In recent years, reproductive health advocates have taken a page from “big pharma” and developed a moderate amount of expertise in advertising emergency contraception and disseminating information about where to obtain it. Although costly, these efforts have met with some success and underscore the need for a more robust and ongoing feedback loop among consumers, health professionals, product manufacturers and advocates. In cultivating this dialogue, it is critical to specify at each step in the process who the specific audience is.

Advertising

The fact that the pharmaceutical industry pours millions of marketing dollars into advertising suggests that it works. According to some industry representatives, it is likely that an advertising campaign for one product will increase sales for other products in the same category. For example, when Plan B advertised in New York City subways, sales of both Plan B and Preven rose. The benefits of switching products to OTC status may include an increase in direct-to-consumer advertising, increased competition and lower prices. The success of the recent Ortho Evra patch ads, which many meeting participants said they had seen, suggests that the positive attributes of a contraceptive can be used effectively to promote the method. The advocacy community needs to capitalize and improve on the proven strategy. However, as the earlier anecdote of the patch suggests, the aim must be to create advertising that does not just sell a method but provides information and education as well.

Social Marketing

Many participants raised the idea of applying social marketing techniques used in other countries to educate consumers and market contraceptives in the United States. Participants suggested marketing contraceptives at hair salons, Tupperware parties, places of worship and bars, and in public bathrooms. Participants also mentioned tapping socially conscious, widely popular businesses for public education campaigns (e.g., the condom ads that were produced by Kenneth Cole) and finding celebrity spokespeople.

Providers

Research has shown that many women consider health care providers to be a vital, trusted source of information. Unfortunately, insurance companies do not reimburse health care professionals for educating their patients. It was also noted at the meeting that not all women trust health care providers, and that language barriers and a lack of cultural competency among providers can be problems in reaching certain groups of women.

Print Media

Women's magazines and feature stories in the daily news are a top source of health care information for women. The Public Interest Media Group reviewed more than 150 print and broadcast stories to better understand today's story lines related to contraception (see Appendix C for summary report). The report indicated that media coverage of new contraceptive methods generally reflected the information needs and concerns of women and reinforced their expectations about efficacy, side effects and appropriate choices.

In addition, media coverage tended away from the message that each new method was a “breakthrough” or “revolution”; rather, it increasingly emphasized the range of contraceptive options available as the breakthrough. Another trend in the coverage—likely a reflection of how manufacturers have sought to position their products—was a focus on lifestyle (e.g., hectic schedules and the complexities of being a modern woman). “To bleed or not to bleed,” the debate around the health implications of suppressed periods, was a theme in stories that focused on Seasonale.

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The consumer-friendly coverage of new methods left little room for discussion about some of the surrounding policy issues that concern women's health advocates, including the need for public funding and insurance coverage for contraception. Few if any stories pointed out the importance of increasing the number of birth control options to reduce rates of unintended pregnancy and abortion. In addition, the issue of whether new methods would be available to all women was rarely addressed.

Internet

The Internet has rapidly become a leading source of reproductive health information, but there is a need to monitor top Web sites to help them maintain current and accurate content. For example, the Reproductive Health Technologies Project recently conducted a study of information about the IUD on the Internet and found disturbing amounts of out-of-date information and misinformation.³³ In addition to having good information online, placement is also key. One idea is to encourage online dating services to offer advice on contraception.³⁴

Action Steps

Reproductive health and rights advocates from diverse sectors, communities and professional backgrounds must work together to move the contraceptive revolution forward. Ideally, the October 2003 meeting and this report will serve as jumping-off points for determining what more can be done and how organizations can contribute.

Below is a summary of potential action steps that stemmed from the meeting.

Service Delivery

- Arm women with questions to ask their doctors or pharmacists about contraception.
- Develop a strategy for taking an oral contraceptive over the counter.
- Set cultural competency standards and develop training programs across health care systems.

Public and Private Insurance Advocacy

- Pressure states to apply for Medicaid waivers to ensure that OTC products are covered.
- Work toward changes in public health systems that would allow women to obtain OTC and prescription contraceptives at pharmacies without having to pay out of pocket or go to a clinic.
- Use strategies outlined by the National Women's Law Center to empower women to ask for changes to their health plans, including coverage of more contraceptive products and the distribution of oral contraceptives in three-month rather than one-month supplies.³⁵
- Educate women about the new Internal Revenue Service flexible benefit rules regarding reimbursement for OTC contraceptives. (The National Women's Law Center is researching what products are included.)
- Continue to advocate for comprehensive and accurate contraceptive education in schools, the removal of abstinence-only programs and increased funding for comprehensive sex education programs.
- Continue to fight for increased funding for Title X, Title XX and Medicaid programs.
- Encourage women to vote and to consider reproductive health issues when deciding for whom to vote.

FDA-Related Advocacy

- Work with Barr Pharmaceuticals to move toward FDA approval of OTC status for Plan B. (On July 22, 2004, Barr submitted a request to the FDA for a dual label that would make Plan B prescription-only for women aged 15 or younger and OTC for women aged 16 or older.)
- Begin conversations with the FDA about reducing the 12-month study length requirement for contraceptive

effectiveness research. The fact that many methods, including spermicides and the sponge, are not used over long periods makes the 12-month requirement seem irrelevant; requiring three- or six-month studies would be more useful and would help get products to market faster.

- Work with the FDA to modify direct-to-consumer advertising rules so that ads include useful messages rather than an unhelpful string of contraindications listed at the end.

Public Education

- Identify several new celebrity spokespeople who can speak to a variety of audiences about contraception.
- Take advantage of television advertising when possible.
- Identify a corporation that will take on contraception as a cause.
- Utilize social marketing techniques in education campaigns.
- Work with the media to generate more stories on contraception that include "lifestyle" human interest angles (e.g., women who cannot get the method they want because it is not covered by their insurance plan) and the nuances of individual methods, both new and old.
- Work with top health Web sites to make sure they contain accurate and comprehensive information on contraception.

Social Science, Behavioral And Marketing Research

- Conduct communication research that segments audiences to determine appropriate strategies for a range of activities, including clinical trial recruitment, public education and contraceptive development.
- Conduct more Phase IV-type trials that follow HIV research models to examine how consumers actually use various contraceptive methods and to enhance understanding of how lifestyle, attitudes and life stages influence contraceptive use.
- Research potential OTC switches and investigate how well the OTC products would work in real-world settings.
- Conduct more research on the effectiveness of contraceptive counseling.
- Survey employers and third-party private insurers to gather more specific information about the extent of coverage, prescription limitations and cost burden on employees.
- Determine what products are available in Europe but not in the United States, and develop strategies for making these products available to U.S. consumers.

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Appendix A: Meeting Agenda

The Unfinished Revolution in Contraception: Convenience, Consumer Access and Choice

Thursday, October 16, 2003

*Kaiser Public Affairs Center
1330 G Street, NW
Washington, DC 20005*

8:30–9:00	Continental Breakfast
9:00–9:30	Welcome and Introductions
9:30–10:00	Setting the Stage <i>Kirsten Moore, Reproductive Health Technologies Project</i> Closing the Gap Between Consumers' Needs, Preferences and Options <i>Jacqueline Darroch, Alan Guttmacher Institute</i>
10:00–11:30	New Models of Service Delivery <i>Moderator: Beverly Winikoff, Gynuity Health Projects</i> <ul style="list-style-type: none">• Expanded prescriber authority• Streamlined options• Nonprescription options• Expanded insurance coverage
11:45–1:00	Product and Regimen Innovations <i>Moderator: Charlotte Ellertson, Ibis Reproductive Health</i> <ul style="list-style-type: none">• Dual methods• Innovations in hormonal methods• SPERMS, SERTS and SARTS• Research and development• Bringing existing product labels up to date
1:00–2:30	Lunch
2:30–4:30	Helping Consumers Choose <i>Moderator: Nanette Falkenberg, Independent Consultant</i> <ul style="list-style-type: none">• What is the model?• Sexuality education• Patient/provider interaction• Direct to consumer ads• Activist campaigns
4:30–5:00	Closing Remarks
5:00–7:00	Reception to Honor Sharon Camp

Appendix B: Participant List

Adwoa Agyeman Moriah Fund Washington, DC	Charlotte Ellertson Ibis Reproductive Health Cambridge, MA	Silvia Henriquez National Latina Institute for Reproductive Health New York, NY
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Marie Bass DDB Bass & Howes Washington, DC	Lawrence Finer The Alan Guttmacher Institute New York, NY	Elof Johansson Population Council New York, NY
Jane Bogges Pharmacy Access Partnership Oakland, CA	Michelle Fox University of Maryland Baltimore, MD	Susan Johnson National Campaign to Prevent Teen Pregnancy Washington, DC
Toni Bond African American Women Evolving Chicago, IL	Beth Fredrick The Alan Guttmacher Institute New York, NY	Harry Jonas UMKC School of Medicine Kansas City, MO
Heather Boonstra The Alan Guttmacher Institute Washington, DC	Leslie Furlong US Food and Drug Administration Rockville, MD	Bonnie Scott Jones Center for Reproductive Rights New York, NY
Lance Bronnenkant Barr Laboratories Plainsboro, NJ	Jacqueline Gardner University of Washington Department of Pharmacy Seattle, WA	Michael Kafritsen Ortho-McNeil Pharmaceuticals Raritan, NJ
Marianne Callahan CONRAD Arlington, VA	Melanie Gold University of Pittsburgh School of Medicine Pittsburgh, PA	Marilyn Keefe National Family Planning and Reproductive Health Association Washington, DC
Sharon Camp The Alan Guttmacher Institute New York, NY	Alisa Goldberg Planned Parenthood League of Massachusetts Boston, MA	Jacqueline Koenig Reproductive Health Technologies Project Charlottesville, VA
Janet Chapin American College of Obstetricians & Gynecologists Washington, DC	Tracy Graham Family Planning Council Philadelphia, PA	Erin Kramer RESOLVE Somerville, MA
Amy Coen Population Action International Washington, DC	Sarah Grambs Family Planning Council Philadelphia, PA	Anjali Kumar University of California, San Francisco Oakland, CA
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The Unfinished Revolution in Contraception

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Appendix C: Media Analysis

TODAY'S CONTRACEPTIVE STORYLINE: Main Messages in Media Coverage of New Methods*

**A Media Analysis Conducted for
Reproductive Health Technologies Project
by Public Interest Media Group**

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Introduction

Since the birth control pill was first introduced, the media has played a critical role in shaping the public's knowledge and awareness of contraception in the United States. Indeed, U.S. women report that the media is one of their most important sources of information on reproductive health issues. Media coverage has an impact on people's attitudes about whether contraception is important. And it affects the degree to which a particular method is viewed as relevant or appropriate for them or others. Finally, the media can influence debates over public policy that, in turn, can improve or limit the availability and accessibility of birth control options.

Despite its influence and the best intentions of even the most dedicated health journalists, the media is an imperfect vehicle for providing accurate, "unbiased" health information to women. As some experts have noted, the media's approach to reporting on contraception played a key role in a "boom and bust phenomenon" for previous generations of contraception—namely the pill, the IUD, and Norplant. This cycle is characterized by press coverage that first heralds the arrival of a new method—touting its benefits and creating high hopes—but then shifts to limitations, side effects, and/or misuse of the product. Recent trends in the media—such as increased competition, greater sensationalism, and a decline in health-related coverage—do little to improve the chances that this will not occur again.

Between January 2000 and September 2003, the U.S. Food and Drug Administration approved eight new contraceptive products for women, and a previously approved method came closer to returning the U.S. market. The media generally bore witness to the approval, introduction, and re-emergence of these contraceptive methods, although the extent of coverage varied significantly by product type. To better understand today's contraception "story lines," the Reproductive Health Technologies Project commissioned the Public Interest Media Group to analyze this recent media coverage.

To that end, PIMG reviewed more than 150 print and broadcast stories about Lunelle, Mirena, NuvaRing, Evra, Seasonale, Today Sponge, and Essure—from a range of national and regional outlets (see Methodology and Appendix)—in an effort to shed light on the following questions:

- *How is the media treating the new generation of contraceptive methods?*
- *What are women being told about these options?*
- *Does the coverage reflect women's contraceptive needs and desires?*
- *How are women's attitudes and concerns represented?*
- *Has contraception become a part of the "mainstream"?*

*This report has been edited into an executive summary. For the full report, contact RHTP or PIMG.

The Unfinished Revolution in Contraception

Findings

The main messages in the media coverage of new and re-emerging contraceptives fit into two general categories:

- *Consumer health information, including a method's effectiveness, its risks and benefits, and the impact it has on a woman's fertility; and*
- *"Lifestyle" concerns, namely how different methods affect a woman's daily life, including their impact on her menstrual cycle schedule*

Within these two categories, the messages appear to be:

- *They're great, but they're not always perfect*
- *You can get (some of) what you want*
- *Options and alternatives, not magic bullets*
- *To bleed or not to bleed... that is the question*

Specific findings about each category and message are set out below.

Health Information

They're Great... But They're Not Perfect

Effectiveness: Pregnancy prevention is the primary purpose of contraception—and women cite effectiveness in this area as their number one concern when it comes to choosing a birth control method. Not surprisingly, then, one of the most common media messages about new and re-emerging contraceptives is that they are “effective”—with roughly two-thirds of all stories using the term. Frequently, these stories go on to cite specific data regarding efficacy rates, and journalists and women's health experts often emphasize that these results reflect consistent and correct use.

The methods most likely to be explicitly cited as effective were the Today Sponge, Mirena, and Evra. Two of these deserve additional note:

- *Today Sponge: Every article reviewed about the Today Sponge described it as “effective,” but nearly three-quarters also acknowledged that the efficacy rate is significantly lower than those for hormonal methods.*
- *Evra: While three-quarters of the stories said that the patch is effective, one-quarter specifically noted that efficacy rates were less for women weighing close to 200 pounds or more.*
- *Seasonale: This method was least likely to be described as effective at preventing pregnancy, with only two in five stories making this claim.*

Safety: Women report that “no health risk” is the second most important factor in choosing a contraceptive method, and experts argue that women have a low tolerance for side effects because contraception is considered “well care.” Overall, a third of the stories about new hormonal-based contraceptives mention risks and side effects associated with the hormones themselves. The coverage often likens these to the risks and side effects associated with oral contraceptives, which remain the most common method of reversible birth control even though women continue to express concerns about hormone use. NuvaRing stories contained the most mentions of the risks and side effects of hormonal contraception, with nearly two-thirds describing them—and an almost equal number characterizing them as less than the pill. Coverage on Evra was the next as likely to mention that it has risks and side effects similar to the pill, with this message appearing in almost half of the stories.

Messages about a few, non-hormone-related risks and side effects of these same methods are also worth noting:

- **Mirena:** More than one-quarter of the coverage about this method contained the caveat that IUD use is associated with increased risk for pelvic inflammatory disease, and more than a third referred to problems associated with earlier IUD's (including specific references to the Dalkon Shield).

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- **Evra:** Nearly a quarter of stories mentioned that some women may experience skin irritation from the patch.
- **NuvaRing:** One out of every five stories referenced the possibility of vaginal discharge or vaginitis.

Coverage of non-hormonal methods almost never mentions risks or side effects.

STD/HIV Prevention: When women are asked what matters most in choosing a method of contraception, protection against STD and HIV transmission ranks alongside safety and—in some surveys—almost equal to pregnancy prevention. However, none of the seven new and re-emerging methods provide any protection against transmission of STDs or HIV—and only one out of every six articles indicates that. References to this fact appear most often in stories about the Today Sponge, perhaps reflecting efforts to counter women’s expectations that a barrier method containing nonoxynol-9 might have a protective effect.

Fertility: Women’s intentions about whether and when to have children also affect which method of contraception they choose. Only about one in six articles about reversible methods explicitly discusses return to fertility, with most noting how quickly it occurs. Stories about Lunelle were the most likely to send this message, one of the key characteristics that distinguish Lunelle from Depo Provera.

Lifestyle Concerns

You Can Get (Some of) What You Want

Make it easy: According to recent surveys, more than half of women consider ease of use to be a very important factor in choosing their method of contraception. And this is the most common “lifestyle” message the media is sending about new and re-emerging birth control products. At least two of every five articles describe specific methods or the recent trends in expanded birth control options as “easy/easier” and/or “convenient/more convenient” contraception. Moreover, these views are virtually unanimous, expressed by journalists, health experts, women, and pharmaceutical representatives alike.

The contraceptive methods most likely to be described as easy or convenient are also the newest arrivals on the hormonal birth control scene—NuvaRing, Evra, and Seasonale—perhaps reflecting more recent efforts by the women’s health community and product manufacturers to emphasize these characteristics.

Longer-term choices, not daily hassles: Oral contraceptives remain the leading method of reversible birth control today, yet the pill often gets a bum rap in coverage about new hormonal methods. Almost a third of the articles discussing Lunelle, NuvaRing, and Evra explicitly contrasted their weekly or monthly regimens with the daily requirements of oral contraceptives. And references to busy lives, crazy schedules, and the realities of being a “modern woman” were common. A handful of these articles went so far as to say that women have had their “fill of the pill,” are “pill weary,” or just plain “hate the pill.” Women’s reported desire to be freed from the burden of remembering to take a pill at the same time each day was most pronounced in stories about Evra, nearly half of which made this point.

Nothing interferes, nobody knows: Surveys indicate that between half and three-quarters of women consider it at least somewhat important that their contraceptive method not interfere with intimacy/sexual pleasure or be otherwise “discreet” (i.e. not be visible or not require their partner’s involvement to be effective). With a few notable exceptions, the media is not sending the message to consumers that the new methods meet these criteria. The Today sponge, which is described this way, and Evra, which is not, provide interesting and differing case studies:

- **Today:** Nearly two-thirds of the stories about the sponge mentioned that this is an over-the-counter option that women can control—and that characteristic helped win the sponge such a loyal following. (In fact, all of the coverage about Today underscored how popular it was, and the vast majority specifically referenced a now-infamous episode of *Seinfeld* in which one character hoards sponges after learning they are being taken off the market and subjects potential partners to a litmus test to see if they are “spongeworthy.”)

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- **Evra:** The patch manufacturer's numerous statements that Evra is "a discreet form of birth control" seem to be falling on deaf ears in the media. This characteristic is almost never mentioned, and the few references that do exist are just as likely to send the opposite message.

Access: Issues affecting women's access to contraception—such as costs—are of great concern to the women's health community, but are largely overlooked by the media. About half of the coverage about specific methods of contraception listed basic consumer price information—with about half of those making comparisons to existing methods such as the pill. But only a handful of stories noted that a woman's ability to obtain contraception or choose the method that is most appropriate for her is influenced by the cost and/or whether there is private insurance coverage or public funding available.

Similarly, service delivery issues—such as frequent physician visits or the impact of pharmacy access—were only mentioned in the stories about two methods: Lunelle and Today. More than half of the stories about Lunelle (prior to the recall) noted that the need to make monthly visits to a health care provider might prevent women from selecting this method. Almost all of the stories about the Today sponge at least implicitly connected its popularity to its over-the-counter status.

Options and Alternatives, Not Magic Bullets

Because media coverage about contraception is usually prompted by an event related to a specific product, at least four out of five stories focused solely on one method. Yet a significant proportion of the coverage sends at least the implicit message that women have a range of contraceptives available today. For instance, one-third of the coverage used terms such as "option," "choice," or "alternative" to describe the newly approved or introduced product in question.

Additionally, a surprisingly small proportion—half a dozen of the roughly 100 stories about a single method—called that contraceptive a "breakthrough" (Cosmo about Evra), a "revolution" or "revolutionary" product (NBC about Mirena and CBS describing Evra), "perfect" (Self on Mirena), or "the best invention" (Time on NuvaRing and Evra). In fact, the message that there has been a "breakthrough" or "revolution" or "perfect" way to prevent pregnancy was far more likely to be used to describe the *trend* toward providing women with more contraceptive options than to define a particular method.

To Bleed Or Not To Bleed... That is the Question

The media sends a conflicted, complex message about menstruation and women's views about their monthly cycles. On the one hand, periods are called everything from "a drag" to a "hellish curse"—meaning that approval of Seasonale may, as CBS News put it, "have a dramatic effect on women's daily life (sic)." Not surprisingly then, there were more stories dedicated specifically to Seasonale and menstrual suppression than to every other new or emerging contraceptive except Evra.

On the other hand, many media outlets were quick to note the "controversy" over skipping periods—and nearly half of the stories raised questions about whether Seasonale could have negative long-term health consequences or, ironically, send a negative message about menstruation. The debate over menstrual suppression was treated as a serious health matter, with medical arguments and experts appearing to argue both sides of the question. The same was not always true for the media's portrayal of women's reasons for choosing this method: stories cited Seasonale's pluses for vacation planning and wardrobe choices almost as often as its positive health effects.

Finally, messages about monthly bleeding—both positive and negative—were not limited to coverage of Seasonale. Stories about Mirena were almost as likely to mention its ability to lessen a woman's monthly bleeding as to discuss the product's effectiveness in preventing pregnancy. Meanwhile, the message that women continue to get monthly periods with NuvaRing and Evra was just as common as discussion of the products' risks and side effects.

Conclusion

Over the last three years, the United States has witnessed an unprecedented, exponential increase in the number of contraception options available to women. In many cases, these are new variations on old themes—new delivery systems, changed regimens, less invasive procedures.

Media coverage of these new and re-emerging contraceptives echo women's concerns and needs, with much of the coverage focusing on the top characteristics that matter to consumers in choosing a contraceptive method. The upshot? Contraception is getting better and better. The new methods are highly effective at preventing pregnancy. They contain few—if not fewer—risks and side effects. And, perhaps the best news of all, they are more suited to women's lives today.

It appears the media is doing at least a fair to middling job in providing consumers with the basic health information about contraceptive methods—when they report about them, that is. A significant proportion of stories—although not the majority—acknowledges at least some of the risks, side effects, and limitations of particular methods. And, in recent years, there have been few overblown claims that a single contraceptive method is the “be-all, end-all” for every woman or will forever alter the world of pregnancy prevention. It remains to be seen, however, whether the media coverage about this new generation of contraceptives contains enough nuance to withstand future reports of health problems associated with these new methods should they arise. To date, few have been truly put to the test.

Recent media coverage also provides important insights into how our society views contraception. The media's apparent increase in emphasizing the idea of “options” and “alternatives,” coupled with coverage that sends the message that new and re-emerging contraceptive methods can and should “fit women's lives,” seem to reinforce the notion that it is legitimate to expect that preventing pregnancy not be a Herculean task.

Equally important is what the media is not saying. Without exception, the stories about new and re-emerging methods never question the need for options to prevent pregnancy or report opposition to the overall notion of contraception. There may be debate over whether a specific method provides benefits or poses risks, but there is no debate over whether women and couples should be able to prevent pregnancy. In other words, contraception has become a part of mainstream thinking and everyday experience.

At the same time, however, when the media covers the emergence of new contraceptives, it seldom draws conclusions about the important connection between the expanding the number of birth control options and reducing rates of unintended pregnancy and abortion. Consumer-focused coverage is unlikely to explore whether new contraceptive methods will actually be available and accessible to women—an issue that can bring into the public eye some of the reproductive health community's broader policy goals, such as the need for public funding and insurance coverage for contraception. Working with journalists to better make those links can provide both a challenge and an opportunity for women's health advocates.

The Unfinished Revolution in Contraception

Appendix 1: Methodology

Public Interest Media Group identified significant events (such as FDA approval, product launch/distribution, or other key product announcements) from January 1999 through September 2003 for eight methods of contraception: Lunelle, Mirena, NuvaRing, Evra, Seasonale, Today, Essure, Lea's Shield, and FemCap.

To capture stories prompted by those events, PIMG conducted searches of the Nexis database for stories containing the terms "contraceptive," "contraception," or "birth control" and the specific product name or unique identifying characteristics (such as "patch," "sponge," "monthly shot," and "IUD") in:

- 4 major wire services (Associated Press, Knight-Ridder, Scripps-Howard, and United Press International) and PR Newswire from January 2000 through September 2003
- 3 national newspapers (New York Times, USA Today, and Washington Post) from January 1999 through September 2003
- 2 national newsweeklies (Newsweek and Time) from January 1999 through September 2003
- 6 women's magazines (Cosmo, Essence, Glamour,* Latina, Marie Claire,* and Self*) from June 2000 through September 2003 (*not available on Nexis; stories identified instead through New York Public Library database and PIMG own archives.)
- 3 national broadcast TV outlets (ABC, CBS, and NBC)
- 10 regional newspapers (Atlanta Journal-Constitution, Arizona Republic, Boston Globe, Chicago Tribune, Daily News, Denver Post, Los Angeles Times, New York Post, Oregonian, and St. Louis Post-Dispatch); although roughly half of the stories appearing in these outlets were drawn from wire services that were also part of the search, these were not treated as duplicates because local journalists often edit wire stories before they appear in the regional outlets.

Please note: An initial search of three-month intervals starting two weeks before the significant event dates yielded fewer results than we had hoped—thus prompting our second round of the larger, multi-year searches listed above.

Based on the findings of these searches, PIMG selected for analysis 120 stories related to seven individual products (Lunelle, Mirena, NuvaRing, Evra, Today, Seasonale, and Essure) and 19 stories covering at least two of these methods. Because of the severe underreporting of Lea's Shield and FemCap, PIMG felt it necessary to exclude them from our analysis.

