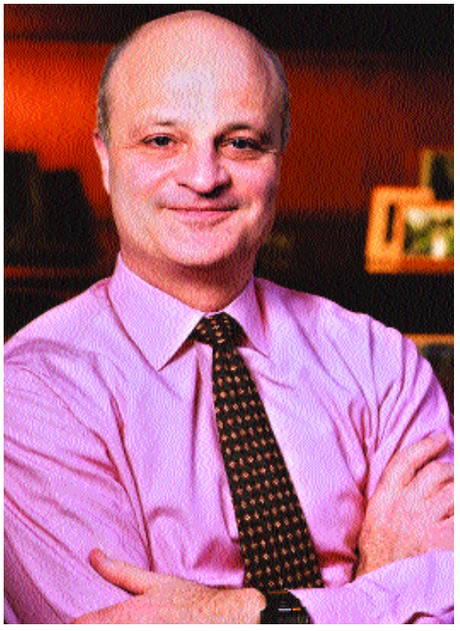
Conquering the Market

ONE SEGMENT AT A TIME

To achieve market share for its cervical-cancer test, Cytyc marketers must switch physicians, labs, and managed-care organizations from the established standard of care.

By Virginia Kirk



PATRICK SULLIVAN, CEO AND PRESIDENT

A best-in-class sales team and superior product attributes are driving sales of Cytyc's cervical-cancer screening device.

When the FDA says your company's test for detecting cervical cancer is more accurate than the universally known and respected standard, the Pap smear, market adoption should be fast and easy.

But in today's complex world of managed-care reimbursement, it's not that easy or fast. However, after five years Cytyc Corp. has captured 46% of the U.S. Pap test market with its ThinPrep System, and signs for continued growth all look good.

"We expect to exceed 50% domestic market conversion by year end," says Patrick J. Sullivan, CEO and president. "This growth has been driven by the combination of our proven marketing strategy, best-in-class sales team, and superior technology."

Cervical cancer screening has been conducted since the late 1940s using the Pap smear, a test developed by Dr. George Papanicolaou. In the United States, widespread and regular use of the Pap smear as a screening test has contributed to a greater than 70% decrease in mortality from cervical cancer. The Pap smear is currently the most widely used screening test for the early detection of cervical cancer in the United States.

In spite of the success of the Pap smear in reducing deaths due to cervical cancer, the test has significant limitations, including inadequacies in sample collection and slide preparation, slide interpretation errors, and the inability to use the specimen for additional diagnostic tests. These limitations result in a substantial number of inaccurate test results, including false negative diagnoses.

A false negative diagnosis may allow the disease to progress to a later-stage of development before being detected, thereby requiring a more expensive and invasive course of treatment and diminishing the likelihood of successful treatment.

Cytyc officials believe that the ThinPrep System offers a number of benefits which address limitations of the conventional Pap smear method, including improved accuracy in the detection of cervical cancer and precancerous lesions, standardization and simplification of the sample preparation process, the ability to permit multiple tests to be conducted from a single sample, improved productivity in screening by reducing cytotechnologist fatigue, reduced incidence of false negative diagnoses, and the time required to examine each slide.

The ThinPrep System, which was originally cleared for marketing as a replacement for the conventional Pap smear method for cervical cancer screening, consists of the ThinPrep Processor and related disposable reagents, filters, and other supplies.

Company executives knew they had a superior product, but the challenge was to overcome the natural propensity of physicians to stick with the

How ThinPrep Works

The ThinPrep System takes samples of cervical cells, rinses them into a vial filled with a preservative solution and sends them to a lab equipped with a ThinPrep processor. At the lab a filter separates cells from blood, mucus, and inflammation and then collects the cells on the surface of the filter membrane. The processor then automatically calculates the number of cells collected and inverts the filter against a slide, which provides a very clear, representative sample. Cytyc advertises that ThinPrep's liquid-based monolayer specimen preparation leads to fewer false negatives because it captures all of the cervical cell sample.

The ThinPrep process can also be used to test for diseases such as HPV, chlamydia, and gonorrhea and the company is continuing to work on those uses.

60-year-old standard of care. A critical element of the company's strategy was to promote the safety and efficacy of the ThinPrep System to third-party payers, healthcare providers, and clinical laboratories.

Cytyc's focus is on obtaining coverage and reimbursement from major U.S. national and regional managed-care organizations and insurance carriers. Most of the third-party payer organizations independently evaluate new diagnostic procedures by reviewing the published literature and the Medicare coverage and reimbursement policy on the specific diagnostic procedure.

In the United States, the current rate of reimbursement to laboratories from managed-care organizations and other third-party payers to screen conventional Pap smears ranges from about $6.00 to $36.00 per test, with $17.00 as the most common rate of reimbursement. The cost per ThinPrep Pap Test, plus a laboratory mark-up, is $11.25.

At the start of 2000, ThinPrep was on the formularies of 190 insurance plans. By June 2001 that number was 351, covering 200 million members. According to Cytyc officials, there are about 600 managed-care organizations and other third-party payers in the United States. In addition, the ThinPrep process is used in 935 labs in the United States; these labs account for 80% of all Pap smear tests in the country.

The company first scored managed-care success in Massachusetts with an early formulary win when United Healthcare signed on. Then Blue Cross of Massachusetts decided to cover the test at a higher reimbursement rate. That led Harvard Pilgrim and Tufts Health System to put the Cytyc test on their plans. The salesforce then moved on to Rhode Island and Connecticut, with some small converts in Texas and Colorado.

"Our big win came when Prudential, Winetka, and Aetna agreed to cover ThinPrep," says Craig P. Sands, VP of sales and marketing. "They had been holdouts and had publicly stated they wouldn't cover our test."

Targeting all three customer populations — managed care, physicians, and laboratories — was a necessity, according to company officials. The labs wouldn't buy the system if the doctors didn't order it. And doctors wouldn't order it if the insurance companies wouldn't pay. And the insurance companies wouldn't pay if doctors didn't say they wanted it.

Defining the market

Dorland Sweeney Jones Health Communications, the agency of record for Cytyc, was instrumental in helping the company launch the test.

"We named and launched the ThinPrep Pap Test and worked closely to manage the

ThinPrep Time Line

Cytyc's ThinPrep System allows for the automated preparation of cervical cell specimens on microscope slides for use in cervical cancer screening, as well as for the automated preparation of other cell specimens on microscope slides for use in nongynecological testing applications.

MAY 20,1996 The company received premarket approval (PMA) from the FDA to market the ThinPrep System for cervical cancer screening as a replacement for the conventional Pap smear method.

NOV. 6, 1996 The FDA cleared expanded product labeling for the ThinPrep System to include the claim that the ThinPrep System is significantly more effective in detecting low-grade squamous intraepithelial lesions and more severe lesions than the conventional Pap smear method in a variety of patient populations. The expanded labeling also indicates that the specimen quality using the ThinPrep System is significantly improved over that of the conventional Pap smear method. The company believes that the ThinPrep System improves accuracy in the detection of cervical cancer and precancerous lesions by making the slide more representative of the patient's clinical condition, improving preservation of the sample, standardizing the presentation of cells on the slide, and reducing the presence of mucus, blood, and other obscuring debris.

FEB. 25, 1997 The FDA approved the company's supplemental PMA application for use of a combination of an endocervical brush and spatula sampling devices, a commonly used method of collecting samples for conventional Pap smears.

SEPT. 4, 1997 The FDA approved Cytyc's supplemental PMA application for the testing for the human papillomavirus (HPV) directly from a single vial of patient specimen collected in a ThinPrep solution using Digene Corp.'s Hybrid Capture HPV DNA Assay.

1997 Cytyc commenced the full-scale commercial launch of the ThinPrep System for cervical cancer screening in the United States.

1998 Cytyc commenced the full-scale commercial launch of the ThinPrep System for cervical cancer screening in selected international markets.

MARCH 1999 The FDA approved the use of Digene Corp.'s Hybrid Capture II HPV DNA Assay from a single vial of patient specimen collected in ThinPrep Solution.

JANUARY 2000 Cytyc entered into a supply and co-marketing agreement with Quest Diagnostics Inc. to market the ThinPrep Pap Test as Quest Diagnostics' exclusive liquid-based cervical cancer screening methodology.

MAY 2000 The FDA approved the ThinPrep 3000 Processor, Cytyc's next-generation processor for automated sample preparation.

OCTOBER 2000 Cytyc entered into an agreement with Roche Diagnostics Corp., exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for chlamydia and gonorrhea using Roche's Cobas Amplicor CT/NG Test directly from the ThinPrep collection vial. The companies also intend to explore the potential for collaborating on a portfolio of additional screening and diagnostic tests based on the companies' respective technologies.

DECEMBER 2000 Cytyc began clinical trials of the ThinPrep Imaging System to aid in cervical cancer screening.

JANUARY 2001 Cytyc entered into an agreement with Digene Corp., exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for HPV using Digene's Hybrid Capture II HPV DNA Assay directly from the ThinPrep collection vial. The companies expect that the co-promotion program will initially focus on promoting Digene's HPV DNA test, using the residual material in ThinPrep collection vials, as the optimal patient management strategy for borderline cytology results.

marketing to physicians, labs, managed care, and consumers," says Kate Maguire, executive VP, group management supervisor, Dorland Sweeney Jones. "We happened upon each other in 1995 when Cytyc was a $5 million to $8 million company and now the company has well over $200 million in sales."

Cytyc operated with substantial losses before 2000, primarily as a result of expenses connected to obtaining FDA approval of the ThinPrep product, engineering and development of its system, and starting up a marketing and salesforce. According to Ms. Maguire, the agency knew that Thin Prep would be a winner if Cytyc could convince managed care to reimburse for the test. "We spoke with physicians, who told us if the managed-care companies will pay for this better test, this is the future," Ms. Maguire says.

Cytyc's high penetration into the Pap test market is partly due to the product's approved FDA labeling, which states that ThinPrep is more effective than its competitors. ThinPrep has been rated significantly more effective in detecting low-grade squamous lesions and more severe lesions than the conventional Pap smear method in a variety of patient populations.

"Efficacy numbers are good," Ms. Maguire says. "Cytyc just got new labeling stating that the ThinPrep finds 59% more high-grade lesions; these are the lesions most likely to progress to cervical cancer, and that's a very compelling statistic. Tests like this are the future and for every 50 that come along, only one will make it to market."

CYTYC IN THE NEWS

FOR CYTYC, A BOXBOROUGH, MASS.-BASED DIAGNOSTIC COMPANY AND MANUFACTURER OF THE THINPREP PAP TEST SYSTEM, WHICH IS EXPECTED TO ATTAIN A 50% MARKET SHARE, THE GOOD NEWS KEEPS GETTING BETTER:

- After the second quarter of 2001, Cytyc reported revenue of $53 million, a 12% increase from the first quarter of 2001 and a 58% increase from the previous year.
- The FDA recently granted premarket approval to Cytyc to include data in its packaging describing how well the ThinPrep Pap Test system detects high-grade lesions .
- Research analysts covering Cytyc all rank the Nasdaq-listed stock as a buy.
- Cytyc's salesforce to obstetricians and gynecologists is the country's second largest, behind Johnson & Johnson.
- The company's technological platform has led to strategic alliances with Roche and Digene.

Cervical cancer is one of the most common cancers among women throughout the world. Cervical cancer is preceded by curable precancerous lesions that progress without symptoms over a period of years until they become invasive, penetrating the cervical epithelium (cellular covering) and entering the bloodstream or lymph system. To detect these precancerous lesions, gynecologists in the United States typically recommend annual screening examinations.

If detected in the precancerous stage, virtually all cervical cancer cases are preventable. The treatment of cervical cancer after it reaches the invasive stage may require surgery, including a hysterectomy, and chemotherapy or radiation treatment, which are difficult, expensive and may not be successful.

A market challenge

Bringing the product out in the mid-1990s was a challenge. The company had to contend with a changing managed-care environment and the industry's long attachment to the conventional Pap smear.

After a long research process, Cytyc's marketers went all out with a campaign targeting all three audiences – targeting just physicians or just managed care or the labs wouldn't make a difference.

In the beginning, Mr. Sands says marketing and sales efforts were begun using contractual employees from Snyder Healthcare Services. The contract salesforce called on physicians, managed-care companies, and labs to show them the data on how well ThinPrep worked.

Cytyc now employs 242 people in sales and marketing, most of whom were Snyder sales people.

"I found that contractual sales was a good way to start our work and to evaluate people," Mr. Sands says.

Salesforce marketing initiatives for physicians include one-on-one meetings and dinner events. The company also uses journal advertising and is now venturing into direct-to-consumer advertising.

The direct-to-consumer ads began appearing in the Boston area and are now in pilot programs in New York. According to Ms. Maguire, in New England, the first market targeted for DTC, market share increased from 8% to more than 30% after six months.

"In other markets — New York, Washington D.C., Baltimore — we saw the same increases," Ms. Maguire says. "The company has about a 50% share of the national market in the areas where we've done DTC, in many cases market share is more than 80%. We are currently running a DTC campaign in San Francisco."

The direct-to-consumer campaign encompasses a combination of print and TV, shows that reach women who are 35 years old or older.

"The company still needs to be aggressive," Ms. Maguire says. "A 50% market share does not mean the job is done. It's now about continuing to turn the category on its ear. ThinPrep is now approved as a Pap test and an HPV test; it's not just a replacement for the Pap test, but a whole new test. Our job going forward will not be easier, but different, and that will keep Cytyc ahead of anyone else developing the same type of test."

Recently, the American College of Gynecologists retired its position on the conventional Pap smear test being the standard of care. Cytyc officials say the ruling should motivate more physicians to recommend ThinPrep.

Ryan Rauch, an analyst at Adams, Harkness & Hill, San Francisco, believes that as a medical-device company, Cytyc couldn't have done any better.

"It's very difficult for any medical device company to get to the point that Cytyc has with 46% of the domestic market share," Mr. Rauch says. "FDA's label allowing Cytyc to promote ThinPrep as being superior to the conventional Pap and the recent FDA approval for detection of high-grade lesions are major impediments for any competitor to overcome."

KATE MAGUIRE

Dorland Sweeney Jones knew ThinPrep would be a winner if Cytyc could convince managed care to reimburse for the test.

According to Mr. Rauch, Cytyc is a core holding in the mid-cap medical device world. Though concerned about Cytyc's devaluation and $3 billion market cap, he is pleased to see that the company has begun to leverage its core technology into new areas, evidenced by the chlamydia arrangement with Roche now approaching FDA approval, and a cross-selling agreement with Digene for the company's HPV test. "From every financial parameter, you can't find a company with Cytyc's quality of earnings," Mr. Rauch says.

Thomas Gunderson an analyst at U.S. Bancorp Piper Jaffray believes Cytyc's growth will continue next year. "With market momentum on the company's side now, we think the crossover from new technology to new standard of care is within sight," Mr. Gunderson says. He predicts that the company will hit the 50% conversion point in the third quarter of 2001 rather than the end of 2001 as Cytyc officials thought.✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmalinx.com.

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