



CMO Aligns Functions Locally to Refocus Globally: An Interview with Dr. Ed Bradley

In the last year, the Clinical Operations group at Berlex has reorganized and grown from 104 people to 135 people. Leading the changes and overseeing the growth of the department is Dr. Ed Bradley who joined Berlex at the end of 2001. Vista asked Dr. Bradley for his thoughts on life at Berlex as he approaches his first anniversary with the company.



What are your key responsibilities as Chief Medical Officer at Berlex?

The role of the Chief Medical Officer encompasses several areas of responsibility. The straightforward part of the job involves the line responsibility for Clinical Operations. The Chief Medical Officer also serves as the “go to” person when the company needs a

medical opinion concerning issues of product safety or the ethicality of conducting a trial.

There is another area of responsibility that I regard as important and that is to do everything that I can to bring people together and focus upon the medical work that needs to be done.

How will the reorganizations that have taken place within your area strengthen the company's U.S. clinical development activities?

The merger of the clinical operations functions that occurred in May has given us

more flexibility in allocating our resources among projects. We don't have enough people to do every project and, when you have a good portfolio, that is to be expected. But the reorganization makes it easier for us to reassign people to higher priority projects. Another advantage is that people within each of the departments of Clinical Operations can more easily share their expertise and learn from one another.

Consistency constitutes another benefit. In the past, each group had its own procedures for the various functions. This made it difficult for the departments with whom the groups interacted, such as Regulatory Affairs and Quality Assurance. With more and more of our trials being conducted internationally, it's important that we have a more consistent global focus.

What are your thoughts on creating an effective working environment and how do you see the Company's mission and values supporting this working climate?

When I started my medical career, I never would have thought that I would enjoy the process by which people work or the logistical details involved in getting the job done. The more that I'm responsible for processes, the more enthusiastic I get about that aspect of my job.

I believe in making sure that people understand what they're expected to do and then getting out of their way and letting them do it. I also feel strongly about creating an environment where employees feel free to speak up. It concerns me to hear that some people are afraid to take an action or voice

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Corporate Development Program Builds Bench Strength and Enhances Personal Growth

Continuous on-the-job growth and development of people is an important dimension of any high performance organization. To better prepare future leaders, the Company recently introduced the Berlex Corporate Development Program (BCDP). This six-month learning experience provides participants with opportunities to focus on their personal development needs, while gaining a broader perspective of the organization as they work on a real-life problem that impacts the business.

Wolfgang Kunze, one of the executive sponsors of the project, provided an overview of the program's significance, "The value of the Corporate Development Program is that it moves away from a theoretical case study and focuses on real issues identified by management at the Organizational Tara meetings. In working on real problems, both the individual and the company benefit as barriers between people and functions are broken down in the process of finding solutions. The result is personal development as well as organizational improvement."

Experience is the Best Teacher

This leadership development program employs an experiential Action Learning Model. Action Learning is a systematic process through which individuals learn by doing. A learning coach guides participants, helping them to achieve balance between solving the problem and addressing their individual learning goals. Participants are encouraged to reflect on what it is that they are

learning and to reframe those experiences to apply to different situations. Nancy Konnerth, Associate Director, Regulatory Advertising & Labeling and a BCDP participant, commented on Action Learning, "Most of us learn by doing a job, but sometimes we are unable to see the big picture and need a different perspective. Action Learning enables us to think 'out of the box', expanding ideas and solutions to meet our corporate objectives effectively."

The Right Problem is as Important as the Right Solution

Selecting a viable action learning problem is a challenge in itself. To provide a valued learning experience, the problem must be a complex one that crosses functions and has no obvious or known solution. The proposed problem must be meaningful to everyone on the team, and lend itself to being resolved within the program's six-month time frame. BCDP member Hans Friedli, Manager, Middle-tier Applications, remarked, "The Action Learning technique that is used to train the participants and, at the same time, get results on a real project is very effective. Most of my teammates learn best, as I do, in a hands-on environment. For Berlex, the BCDP is an opportunity to develop leadership and to address business issues that the company faces."

Prior to the launch of the Leadership Development Program, the program's executive sponsors—Wolfgang Kunze, Bob Chabora, Reinhard Franzen, John Rotondo, and Bob Milos—actually partici-

pated in a one-day session that modeled the program. At this session, the sponsors identified the problems to be assigned to the teams.

Six-Month Pilot Launched

For the pilot, Executive Committee members nominated 14 leadership development candidates who attended an orientation session. Following the orientation, the pilot participants conducted a 360-degree assessment and, based on the feedback they received, established personal learning goals. Two teams were formed and program participants began work on the assigned project and also had the opportunity to share with others their personal learning goals.

One team will explore and recommend ways to ensure that a pool of people with broad leadership capabilities exists and that they are ready to assume executive-level leadership positions in accordance with the needs of Berlex's future growth. The second team is examining to what extent Berlex should use electronic interactions to improve the perception of the Company and its products.

Action Learning in Action

Program participants meet on a regular basis, either face-to-face or via video conference. Meeting time is equally divided between project work and addressing learning goals, with team members providing one another with feedback and support. During the group problem solving sessions, executive sponsors provide support in terms of

for Berlex Imaging, "Experience. Leadership. Vision," and new logo will be launched and displayed on the convention panels at the booth. In addition, there will be planned activities geared at increasing booth traffic and obtaining prospecting information on customers and potential customers. We are also excited that the MAGNEVIST anniversary campaign has been adopted as a Schering global campaign allowing us to work closely with our colleagues in Berlin to achieve our common goal of maintaining leadership in MRI.

Lastly, we are very excited to have recently received FDA approval for the 500 mL pharmacy bulk package of ULTRAVIST®, the first step in a series of life cycle management activities demonstrating our commitment to ULTRAVIST.

Oncology Business Unit

The Oncology Business Unit participated in the 44th Annual American Society of Hematology Convention held in Philadelphia on December 6 through December 10. More than 20,000 clinicians and scientists participated in this conference that provides hematologists from around the world a forum for discussing critical issues in hematology. On Corporate Friday, when ASH provides members of the industry an opportunity to offer their own educational symposia, Berlex held a seminar entitled, 107 Years of Antibody Therapy for Malignancy: Current Directions in the Treatment of Lymphoma and Leukemia.

The November 9th issue of *The Lancet* published an article with the results of a phase 1 pilot study of LEUKINE® in Crohn's disease. The study suggests that LEUKINE may provide a novel approach to treatment of this disease. Unlike traditional treatments such as steroids, LEUKINE is believed to stimulate specific immune system



cells in the gastrointestinal tract that may be impaired in patients with Crohn's disease.

The initial positive results represent an exciting step forward in the future development plan for LEUKINE.

Therapeutics Business Unit

Over the last several months, the Therapeutics CNS Marketing team has successfully launched the Betaseron Education Training and Assistance (B.E.T.A.) Center and B.E.T.A. Nurse initiative for MS patients. Multiple sites across the U.S. provide people with MS new, face-to-face opportunities to learn, interact and share with others. Additional centers are planned for the future.

The B.E.T.A. nurses surround MS patients with support and offer the personal care and education that helps to make therapy as effective as possible right from the start. In terms of customer service provided in support of a therapy, the B.E.T.A. Center program delivers to patients and caregivers a level of care not previously seen in the industry.

Now, in addition to the Nurse Hotline, which is available 24/7, MS patients have access to specialized nurses solely dedicated to providing:

- Personalized SC (subcutaneous) injection training

- Constant and consistent follow-up care
- Scheduled phone calls or personal contact
- Assistance in adjusting to therapy and answers to questions regarding BETASERON® and MS
- Free support programs and seminars on topics such as cognition, symptom management, massage (yoga) and Internet resources, etc.

The one-on-one support and attention available to MS patients through the B.E.T.A. program improves quality of life and patient compliance and helps to strengthen the image of BETASERON with physicians and consumers. The CNS marketing group has worked very hard over the past year to effectively design and to successfully implement this important program.

Please take a moment to check out the MS Pathways website www.mspathways.com and join us in congratulating the team for its outstanding effort!!

MRI and Magnevist — Diagnostic Radiology Success Story

Magnetic Resonance Imaging (MRI) was introduced into clinical practice in the early 1980s. By providing accurate information for the diagnosis and monitoring of disease and injury in a wide range of organ systems, MRI has since emerged as a powerful tool in radiology. In MRI, the patient is placed inside of an MRI magnet that surrounds the patient in a strong magnetic field. During the scan, the patient's body receives pulses of safe, low-energy radio waves. When the pulsing stops, the patient's body emits weak radio signals that are picked up by the MRI receiver coil. A powerful computer translates the signals into MRI images of the body.

Initial expectations for MRI were so high that it was felt that contrast agents would not be needed. However, as clinical MRI experience broadened, it was determined that as many as 12 percent of brain tumors went undetected.

Schering AG, with the introduction of the first MRI enhancement agent, MAGNEVIST®, helped revolutionize the MRI industry. The concept of contrast-enhanced MR imaging improved differentiation of malignancy from normal tissue, primary tumors vs. secondary tumors (metastatic disease), infection and inflammation.

Since its launch 15 years ago, MAGNEVIST has been the leader in the MRI contrast media market, maintaining over 50 percent market share. Sales continue to increase an average of 12 percent per year in the U.S. Today, fifteen years after it launched MAGNEVIST, Berlex continues to be the leader in this market.

Use of MRI Technology Expands

In the last few years, MRI has become increasingly important for diagnosis of the brain and spinal cord. In addition to being a powerful neuroimaging tool, MRI is gaining great interest and is demonstrating clinical utility in body applications, in particular, vascular imaging. However, due to long scan times and motion artifacts, utilization of MRI for vascular imaging was slow until technological advances occurred in the late 1990s.

With the advent of faster machines and improved computing power, Magnetic Resonance Angiography (MRA) is now one of the fastest growing subsegments in MRI, and is gaining increased acceptance in clinical practice. MRA imaging is a type of MRI scan that provides pictures of blood vessels and allows physicians the ability to non-invasively evaluate blood vessels for blockages and disease.

Schering AG Develops New Contrast Agent, MS 325

Although not currently approved by the FDA for this use, existing MRI contrast agents have made a significant impact in increasing the number of MRA procedures. However, these agents are small molecules that distribute and clear from the blood stream in a relatively short time. Therefore, image acquisition has to be performed within a few minutes of contrast administration.

MS 325, which is being developed for use with MRA in the diagnosis of peripheral vascular disease, belongs to a new class of contrast agents, known as blood pool agents, that remain in the

vasculature for a prolonged period of time. MS 325 binds reversibly to human serum albumin, providing brighter images and a longer diagnostic imaging window. Leslie Villarreal, Group Product Director at Berlex, explained that MS 325 with its extended residence in the vasculature, coupled with high-resolution images, will allow for better delineation of the vessels, increase diagnostic confidence and enable more accurate planning for patient treatment. In essence, MS 325 will accelerate the growth of MRA procedures, expanding its use to community hospitals and other institutions that may not have state-of-the-art MRI equipment.



According to Dr. Kohkan Shamsi, Director of Clinical Development Projects in Diagnostic Imaging, "In order to maintain Schering's leadership role in the MR contrast media market, it is essential to develop in a timely fashion new and innovative contrast agents that satisfy unmet medical needs. The development and introduction of MS 325, the first blood pool agent, to the market is one of the key components of the multi-pronged approach that Schering is pursuing to achieve this strategic objective."

The Schering – EPIX Medical, Inc. Joint Venture

MS 325 is being developed together with EPIX Medical, Inc., a

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An Interview with Dr. Ed Bradley

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an opinion or disagree about something because they don't want to offend or anger another person. I tell people that, "If you come here every day, if you try to do your best, if you get work done, Berlex is a place where you don't have to worry about repercussions."

What are some of the critical issues you face in your position? What would you identify as your greatest short-term challenge?

Ensuring that the work is getting done properly is a tremendous challenge. For a variety of reasons, about 70 percent of our work is contracted out. That percentage is too large. In contrast, Schering AG contracts out perhaps about 20 percent of the work and, in Canada and Japan, work is rarely contracted out. Contracting work out is more expensive than doing it in-house, and when the contractors leave Berlex, they take the experience and the training they've received here with them. We need to reduce the amount of work done by contractors.

In terms of my priorities, it goes like this. One, to get the most done that we can for the high priority projects. Two, to give management a realistic estimate of our actual capacities and how efficient they could become. And, three, to work as part of the Schering Group in determining where trials should be positioned. It costs more money to conduct clinical trials in the U.S. than it does in Europe, so we need to identify the right balance.

Recent reports surrounding clinical trial research practices are drawing negative attention from the public and congressional leaders. What are your thoughts on this matter?

First of all, in terms of being forthright about the data and not

putting impediments in the path of investigators to legitimately publish data, Berlex has very high standards. We treat our investigators as scientific colleagues and we believe that patients and the public should have full access to the information needed to make good medical decisions concerning patient care. We absolutely adhere to all of the guidelines about the protection of patient privacy and patient rights.

There's been a great deal of focus upon inappropriate monetary remuneration of physicians and investigator sites. We guard against that in a number of ways. First of all, we have a very transparent CRO and physician contracting process. For a long time, I've had rules about what we will and what we will not do for investigator meetings. No boats. No islands. No golf, spas, or resorts. We just don't do those things. Researchers who have worked with us know that we're good to work with, that the financial support for the conduct of the trials is fair, and that we don't play games.

In terms of business development, what do you see as the Company's greatest potential for growth?

One area where I see a great opportunity for Berlex is in oncology. LEUKINE® was an important acquisition. We've acquired not only a good product but an excellent group of experienced people to complement the oncology expertise that we have in Richmond. We have a good oncology pipeline and the capability of acquiring other significant products.

One of the Company's strategic imperatives is "to design and support development activities that effectively transform technologies into products

of recognized value." In your opinion, how should we measure our success in this area?

It is measured a couple of ways. One is by getting drugs approved for the right indications in a reasonable amount of time. One of the ways that we measure reasonable amounts of time is to benchmark our performance to industry standards. For example, we know how long it should take to write a protocol, set up the database, enroll the first patient. And we must consistently look for ways to improve our performance. Sometimes technological changes need to be made. Other times, the needed improvements are operational. The key is to identify where we might be coming up short and take steps to improve the process. That said, we are also challenged to balance keeping up with the best and, at the same time, maintaining those things about Berlex that distinguish us, for instance, our culture.

What would you like people to know about your life and interests outside of Berlex?

What life outside of Berlex? I live in New Hope, Pennsylvania so I spend a great deal of time commuting. I have children and a granddaughter who live in the Philadelphia area, so I didn't want to move too far from there. My commute goes against the traffic, but it's still close to an hour and a quarter and that doesn't leave much time in the day.

I like what I do. Work for me is an organizing principle of life and it is the chief form of interpersonal interaction that I have and I'm happy about that.

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News From The BUS

Dermatology Business Unit

The dermatology business unit anticipates launching FINACEA GEL® 15% early in 2003. It is an advanced microfinely blended formulation of azaleic acid in a gel base that has been shown to have considerable efficacy in reducing the redness and skin inflammation characteristic of rosacea. Rosacea is a chronic dermatologic condition affecting 14 million Americans.

Preparation for the launch is proceeding on schedule. The launch concept has been developed, appropriately tested and is ready to go. At the current time, we are in the final stages in the development of the sales visual aid. Our publication and public relations plans are ready to be activated.

In a recent meeting of practicing dermatologists, it was noted that FINACEA has a place in the first-line treatment of rosacea, and will be a welcome therapeutic option. Our discussions with the FDA seem to be on track, and they have already approved our production facility in Milan. Divisional sales and marketing management are enthusiastically

awaiting FDA approval that optimistically is expected by the end of the first quarter of 2003.

Female Health Care Business Unit

Members of the Berlex Female Health Care Business Unit recently hosted the 2002 Congressional Staff Tour sponsored by the HealthCare Institute of New Jersey (HINJ). The tour is an annual event which allows members of the staffs of policy makers to visit pharmaceutical companies in NJ to gain an understanding of some of our industry's issues. Our goal in presenting to the staffers was to position Berlex as a resource on female healthcare issues, provide context and a balanced picture of the Women's Health Initiative study, educate staffers on drug development and clinical trials, and raise awareness of our company. Reinhard Franzen, Ed Bradley, Marie Foegh and Don Atkinson were presenters. Representatives of 10 of

the 13 N.J. congressional offices attended the Berlex presentations and then went on to visit Sankyo Pharma, Ethicon and Novartis.

The event also served to raise the staffers' awareness of issues outside of the Women's Health area which are important to Berlex. This included an explanation of the Waxmann-Greenwood bill, which would insure that Medicare beneficiaries have access to all FDA-approved MS therapies, the importance of protecting intellectual property, the issue of drug reimportation, state-mandated contraceptive insurance coverage, and the challenges of the current regulatory climate. Since the staffers advise the legislators on healthcare issues, this was a unique opportunity to directly influence the decision makers, while raising Berlex's visibility.

Imaging Business Unit

The Radiology division in the Imaging Business Unit experienced a very successful 2002. MAGNEVIST® had a stellar year, surpassing previous year sales records and maintaining over 50 percent market share in the MR contrast media market. In 2003, MAGNEVIST will be celebrating its 15th year anniversary. This event provides a great opportunity to reinforce and build upon key messages: Leadership in the MRI market, MAGNEVIST safety and extensive clinical experience and, finally, Berlex Imaging's unsurpassed customer service and support. It is also a good reason to increase awareness within Berlex of the value/profit contributions MAGNEVIST provides to the organization.

We are kicking off the MAGNEVIST anniversary celebration in December at the RSNA (Radiological Society of North America) meeting. The new tag line



Dr. Hubertus Erlen, Chairman of the Board of Directors of Schering AG, was featured on the cover of the November 2002 issue of Pharmaceutical Executive.

You can read the interview on the Berlex Intranet or at www.pharmexec.com.



Berlex Corporate Development Program Objectives

- Develop leadership skills that enable individuals to work above their current levels
- Move more easily from debate to decision-making and implementation
- Hone interpersonal and “consulting” skills to improve the ability to influence others
- Develop self-insight and self-development capability
- Learn more effectively from and through experience

resources and commitments and create an open, supportive, and challenging environment.

“It’s a process that you really have to experience first hand to understand how it works. There’s a continuous cycle of resolving the problem, reflecting on the process, and reframing the experience,” said Bob Ward, Director, Human Resources. “Reflecting is vital to understanding what is being learned from the experience and to recognizing how that learning might apply to other workplace situations.”

Program Outcomes on Target

Among the many outcomes expected from the Corporate Development Program are those that focus on thinking strategically about business issues, shifting from functional to big-picture thinking, and working and leading cross-functionally and globally. Based on the comments of Mark E. Sullivan, Vice President, Research, the program is effectively meeting those objectives. In a recent interview, he said, “The BCDP has given me a broader view of the Company and

the pharmaceutical industry. In carrying out my BCDP project responsibilities, I have had to think beyond my immediate area of expertise. In doing so, I have gained a greater appreciation for the work of my colleagues in other areas and gained a new respect for our EC members who are often faced with making difficult corporate decisions that may impact diverse groups worldwide.”



T Corporate University Complements Local Programs

The concept for the Schering Corporate University dates back to 1999 when the International Management Conference identified Global Management Development as a key success factor for reaching the organization’s strategic goals. Schering Corporate University, a custom-designed general management program, complements existing local development programs.

According to James Shillaber, Director, Human Resources, “The program’s intent is to prepare the management of Schering AG for future challenges by developing strategically relevant skills such as business performance assessment, innovation management, strategic thinking, change management

principles, and leadership capabilities.” The Schering Corporate University targets selected global managers, specifically those who are visibly involved in international projects and processes with high strategic impact. The selection process is driven by senior management and the department of Management Recruitment and Development in Berlin.

Leadership for Growth and Success

Course content for the program’s first module, Leadership for Growth and Success (LGS), was developed with the Cranfield University School of Management in

the United Kingdom where the program is held four to six times per year. The goals of the LGS program are to develop top business management and personal leadership capabilities; to focus strategic orientation on present and future key issues; and to nurture company-wide networking among participants.

Rich Denninger, Vice President Operations, and a participant in 2002, commented, “The program is a unique and effective development experience in that your classmates and learning partners are also your global Schering AG colleagues. The outcome is an enhanced training experience as well as a meaningful,

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MRI and Magnevist — Diagnostic Radiology Success Story

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biotech company located in Cambridge, Massachusetts. Schering is in charge of marketing, management and clinical development in Europe and Japan, while EPIX is responsible for clinical trials and NDA submission in the USA. Upon approval, Berlex will market this product in the USA.

International Clinical Sites to Evaluate Safety and Efficacy

MS 325 is presently in Phase III trials designed to evaluate its safety and efficacy in patients with peripheral vascular disease. Dr. Shamsi, core clinician for MS 325, explained, "MS 325 is a global project in the real sense as it has trial sites located in North and South America, Australia and Europe." Dr. Shamsi added, "To the best of my knowledge, this is the

first time that the Diagnostics Business Unit (BU) has expanded its clinical trial boundaries to include South America and Australia in a Phase III program."

Promising Phase III data were presented to the American College of Cardiology in March 2002. Results of Phase II and Phase III studies have also been presented in interventional radiology conferences and at the MRA Club in the USA and Germany.

In May 2002, Dr. Shamsi chaired an international satellite symposium on blood pool agents at the International Society of Magnetic Resonance in Medicine (ISMRM). Four distinguished speakers and leaders in the field of cardiovascular MRI discussed various types of blood pool agents, including MS 325, and their potential indications. ISMRM

members and affiliates attended the symposium which was very well received.

Future of MS 325

Both Ms. Villarreal and Dr. Shamsi view MS 325 as a very valuable addition to the Berlex portfolio. MS 325 will be the first blood pool agent in the market with MRA indication that will provide state-of-the-art, high-resolution images to improve diagnosis and treatment of patients with peripheral vascular disease. More importantly, MS 325 will enable Berlex to retain its leadership position in the MRI contrast media market. Ms. Villarreal anticipates that MS 325 will be ready for a full-scale launch in early 2005.



Corporate University Complements Local Programs *continued from page 3*

ongoing collaboration resource which is of value to each participant and constructive to the overall corporate culture," he said.

Following completion of the week-long module at Cranfield, participants engage in a six-month LGS in Action exercise that focuses on the practical application of the learning that took place at Cranfield, on networking among participants, and on personal skill development. Throughout this phase of the learning process, participants work on a personal business case, supported by e-learning tools and

professionally coached by members of the Cranfield faculty and Schering process consultants. The module culminates with a virtual final review in the Corporate University team room. During 2001 and 2002, approximately 160 Schering managers took part in the University program.

Second Corporate University Module in Development Phase

From the outset, it was determined that the Schering Corporate University would grow in

an organic way, module by module, targeting different audiences, competencies, and capabilities. The second, yet-to-be-named Corporate University module, which is currently in development, is expected to pilot in 2003. One hundred forty participants are expected to complete the second module in 2003-2004.



VISTA, Winter 2003
Published for the Employees of
Berlex Laboratories, Inc.
340 Changebridge Road
Montville, NJ 07045

Editor: Anne King
Contributing Writers: Mary Ann Kiczek
MAK Communications
Donna Marlowe
Design: PFA Designs, Inc.

The Berlex family of products includes: ACUTECT® (Kit for the Preparation of Tc 99m Apcitide Injection); BETAPACE® (sotalol HCl); BETAPACE AF™ (sotalol HCl); BETASERON® (Interferon beta-1b); CAMPATH™ (alemtuzumab) humanized monoclonal antibody; CLIMARA® (estradiol transdermal system); FERIDEX I.V.® (ferumoxides injectable solution); FINEVIN™ (azelaic acid cream) 20%; FLUDARA® (fludarabine phosphate) For Injection; LEUKINE® (sargramostim); LEVLEN® (levonorgestrel and ethinyl estradiol tablets); LEVLITE® (levonorgestrel and ethinyl estradiol tablets, USP);

MAGNEVIST® (brand of gadopentetate dimeglumine) Injection; MIRENA® (levonorgestrel-releasing intrauterine system); NEOTECT™ (Kit for the Preparation of Technetium Tc 99m Depreotide Injection); QUADRAMET® (Samarium Sm 153 Lexidronam Injection); REFLUDAN® (lepirudin (rDNA) for injection); TRI-LEVLEN® (levonorgestrel and ethinyl estradiol tablets); ULTRAVIST® (brand of iopromide); YASMIN® (drospirenone and ethinyl estradiol tablets).

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