RISK EVALUATION AND MITIGATION STRATEGIES

REMS Take Hold

BY ROBIN ROBINSON

THE NEW LEGISLATION SURROUNDING TOUGHER REMS REQUIREMENTS IS EXPECTED TO EFFECT MARKETING AS WELL AS DRUG DEVELOPMENT— BUT THE IMPACT MIGHT NOT BE ALL BAD.

"The key to mitigating risk is applying a rigorous, science-based approach to understanding how physicians and patients actually use medications."

JEFFREY FETTERMAN
ParagonRx

In the first seven months of 2009, the FDA approved more than 30 Risk Evaluation and Mitigation Strategies (REMS) for both new drug and biologic license applications. There were 24 approvals in 2008, when the REMS legislation took effect. Our experts say it took the industry until the end of 2008 to realize that the new act was going to create a profound sea change in how drugs are developed, approved, and marketed in the United States.

The assumption among some in the industry is that if a drug is required by the FDA to have a REMS, there will be a negative impact on market acceptance. Others say this is not necessarily true. But the first step to creating a positive outcome is to be prepared. One out of every three products that earned FDA approval last year required a REMS.

Part of that preparation should include thinking about how a REMS program can shape the overall marketing strategy. Depending on the requirements in the medication guides, if a communications plan for physicians is necessary, or if there are access restrictions, marketers will want to determine how to put a positive perspective on risk safety management.

"In my experience, many companies do not involve marketing early enough in discussions. They are important participants in the REMS design process because the way the product is commercialized must be consistent with the REMS."

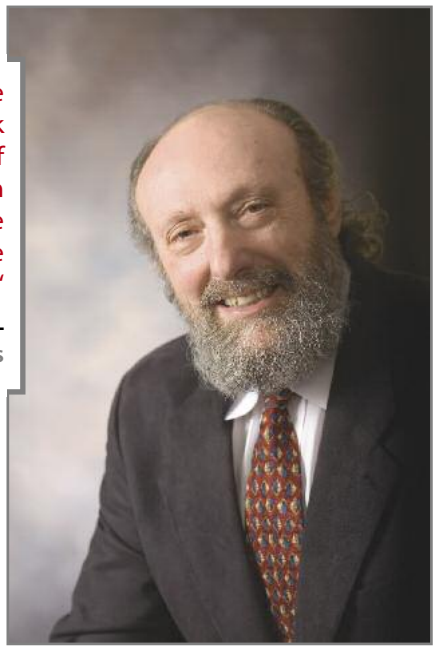
DR. KELLY DAVIS
United BioSource Corp.

REMS AND MARKETING STRATEGIES

PHARMAVOICE ASKED INDUSTRY EXPERTS TO DISCUSS HOW A REMS PROGRAM COULD AND SHOULD POSITIVELY CHANGE MARKETING TACTICS.

ADAMS. Covance. REMS legislation says the program must be commensurate with the risk of the drug. In the future, the industry and the FDA will have to pay a lot more attention to risk management programs while making sure they are not introducing barriers or even perceived barriers or delays in getting patients their medication. For example, Cimzia, the UCB drug approved for the treatment of Crohn's disease, was required to submit a REMS, while similar drugs that were approved earlier did not. But three months or so after approving Cimzia, the FDA went back and required the other TNF blockers to also submit a REMS. This may have been an attempt by the FDA to level the playing field or because the agency realized that if one TNF blocker had significant risk to require a REMS, they all did. Regardless, if the FDA had not required the other drugs to provide a REMS, then Cimzia could have been at a disadvantage. For instance, Covance was working on a risk map paradigm for two drugs that had very similar REMS programs, but one drug had fewer requirements in the medication guide. When it came time to market the drug, the company with the fewer requirements used that fact as a marketing tool — almost like counter-detailing. The company told physicians, "If you use our drug, you only have to do steps X, Y, and Z. If you use their drug, you will have to do A, plus X, Y, and Z." Another issue to consider, especially with opioids, is to what extent will access be restricted? There are some who argue that specialty pharmacies for some drugs will reduce access or slow down the receipt of the product. Take the sale of pseudoephedrine, for example, consumers are required to ask for it at the sales counter and show some identification. That is not much of a barrier, but sales of products containing pseudoephedrine have dropped 20% and the less-effective decongestants have taken their place. In this case, one could argue that a relatively modest barrier has had a fairly significant impact on the legitimate use of the product and an increase in sales for the substitution of a less-effective product. These will all be ongoing issues as the REMS requirements become more specific under medication guides.

> "REMS should not impede the approval process if risk management has been part of the development process from the beginning; in fact, the strategy should enhance the likelihood of approval."
>
> **DR. SIDNEY SCHNOLL**
> PinneyAssociates



> "Keep the REMS as simple as possible to allow effective implementation."
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> **DR. REKHA GARG**
> Amgen

DAVIS. United BioSource Corp. It is important that the overall commercial strategy, tactics, and messages are consistent with the REMS.

FEATURED THOUGHT LEADERS

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SIDNEY H. SCHNOLL, M.D., PH.D. VP, Pharmaceutical Risk Management, PinneyAssociates, which works with clients' marketing, business development, R&D, scientific and regulatory affairs, government affairs, and legal divisions throughout all stages of a product's life cycle. For more information, visit pinneyassociates.com.

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"A REMS that includes elements to ensure safe use could have a very high impact on product messaging."

DAVE PROVOST
INC Research

Educational materials prepared in support of the REMS should not contain promotional claims, but it is important that they be identified with the brand and are consistent in appearance and content with the commercial materials. In cases where the REMS involves greater control of product distribution, such as a performance-linked access system, marketing tactics will need to focus on ensuring that the appropriate patients do not have significant barriers to product access and that prescribers are well-informed about the potential risks and benefits in order for the product to be used safely.

FETTERMAN. ParagonRx. It is important for companies that are designing a REMS to understand that the FDA is looking for risk communications to be completely separate from promotional communications. It's clear that the FDA's concern is that the risk communication will be overwhelmed by promotional communication. In some ways, however, REMS carves out a separate communication program that has to be implemented independently of promotional tactics, which can be a positive thing. While benefit messages are rarely included in a REMS program, there is absolutely nothing that keeps marketers from featuring benefit-risk messages about appropriate use of medications in their non-REMS communications. One advantage of this approach is that it helps the brand meet the REMS' goals. And if it communicates the appropriate aspects of how to manage those risks, physicians will be more confident, and this could lead to an increase in their intention to prescribe. This could have a profound and positive impact on marketing. A REMS design also can impact physician prescribing. ParagonRx conducted a conjoint analysis among 475 physicians to determine what the affect of a risk management plan such as a REMS could have on their intention to prescribe. The survey showed that if the clinicians judged the program to be burdensome or inappropriately designed, it could have a "profoundly negative impact" on intention to prescribe, and in fact reduced intention to prescribe by as much as 58%. Importantly, a program clinicians perceived as beneficial or appropriate could have a "profoundly positive impact" by increasing intention to prescribe by as much as 42%.

"REMS is not just the responsibility of one functional area — diverse internal teams must collaborate along the entire REMS continuum to be effective. For companies that operate in silos, this represents a major challenge."

ILYSSA LEVINS
Center for Communication Compliance (CCC)

LEVINS. CCC. Companies undertaking a REMS program should not have to change marketing goals, assuming they have been committed to fairly balanced promotion and comprehensive education for their promoted drugs all along. They must, however, change their mindset about REMS to avoid the "black-eye syndrome." A REMS requirement should not be perceived as a brand deficit. The industry must view REMS as a positive versus something that is merely required. By employing educational strategies that reframe a REMS in parallel with its implementation, companies can help stakeholders better understand purpose and value. Ultimately, it's an opportunity to proactively manage the communication of critical information. According to Wayne Pines, chair of CCC's advisory board, former FDA associate commissioner, and REMS author, REMS must be viewed by companies "not as a burden, but as an opportunity to position a drug for maximum best use."

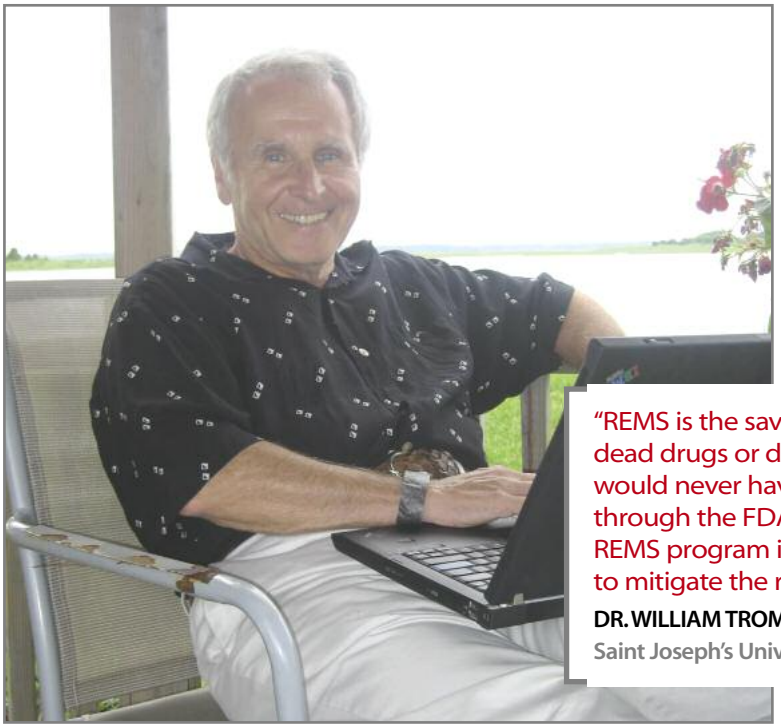
PROVOST. INC Research. How an approved product is presented to the medical and consumer communities will depend on the scope and restrictiveness of the REMS. Most REMS that have been approved to date have been medication guides, which do not restrict a product's distribution or use. These REMS are low impact in terms of product marketing. A REMS that includes "elements to ensure safe use," however, could have a very high impact on product messaging if the elements are restrictive and include a physician and pharmacist certification, or limit where and how the product can be dispensed.

SCHNOLL. PinneyAssociates. Marketing and sales strategies may change based on the nature of the REMS, perhaps influencing rollout strategies or target market priorities. Properly designed REMS should reduce risk and result in a better product on the market. The FDA has been ambivalent as to whether a REMS can be a part of a marketing strategy.

TROMBETTA. Saint Joseph's University. Companies need to be aware that if the FDA wants to see their marketing plans, it may be able to as a way to clarify how target populations were determined. This can be a land mine; companies are not always careful about what they put into some of their marketing documents. Recent litigation involving overaggressive or inappropriate marketing has revealed how numerous pharmaceutical companies have hoisted themselves on their own petards with careless, off-the-cuff remarks about competitors and internal policies and tactics that would have been better not disclosed. This is a critical issue. When writing an article, people do a spell check; I recommend that marketers start doing a language damage control check — what I call an LDC check — even for internal marketing documents. For example, how were the competitors characterized? Is there language that could be viewed as offensive? I'd recommend removing anything about ROI, and try to phrase everything around a new metric, such as better prescribing practices and how patients are likely to benefit.

REMS: BEST PRACTICES

OUR FORUM EXPERTS SAY COMPANIES SHOULD START EARLY AND ANTICIPATE THE NEED FOR A REMS, NO MATTER HOW SAFE THE DRUG. THESE ARE JUST TWO OF THE TIPS THAT OUR EXPERTS OUTLINE AS BEST PRACTICES IN DEVELOPING A REMS PROGRAM.



"REMS is the savior of some dead drugs or drugs that would never have gotten through the FDA without a REMS program implemented to mitigate the risk."

DR. WILLIAM TROMBETTA
Saint Joseph's University

GARG. Amgen. Best practices associated with developing REMS include having a clear understanding of the elements required, obtaining feedback from both internal and external stakeholders, having a dedicated cross-functional team that is empowered to make decisions, and determining roles and responsibilities of each function. It's also important to develop a project management timeline, outline a governance model, determine the vendor depending on the required elements, and keep the REMS as simple as possible to allow effective implementation. Each REMS is unique based on the requirements of the various elements and the product, and the program is probably not related directly to a therapeutic class.

ADAMS. Covance. The questions asked in the 2005 RiskMAP guidance are worth taking a look at. That guidance looked at the type and magnitude of risk, who was at risk, the existence of treatment alternatives — is it a first-line therapy or last resort — preventability of adverse events per appropriate prescribing, and the most important question of all: would a risk map help with appropriate use? These are the same questions to ask today.

DAVIS. United BioSource Corp. The first decision point is whether a REMS should be proposed for the product in the first place. Of course, every product, whether it's a drug or biologic, has risks, but not every product will need a formal REMS. For the majority, the information included in the product labeling will be adequate for risk minimization. The main challenge sponsors are struggling with is whether to proactively offer a REMS at the time of submission or to wait until the FDA asks for it. The answer is obvious in some cases, such as a new compound in a class in which predecessor compounds have a REMS, or in situations where the FDA has given clear direction that a REMS will be required. But in most cases it's a judgment call.

FETTERMAN. ParagonRx. The first priority is to design a REMS that will improve patient safety, and there may be more than one way to do this. The second priority is to create a number of options, then there is an opportunity to define a program that not only improves patient safety but also retains access to medication. If the requirements are burdensome, physicians will avoid using the product and may use a drug that may have an equally challenged risk profile. The third priority is to remember that these programs are only sustainable if they are financially supported by the company, so corporate interests need to be considered in terms of which programs are affordable and sustainable. As long as patient safety and medication access are preserved as priorities No. 1 and No. 2, it is essential for REMS designers to define programs that are fiscally sustainable. Because REMS are relatively new, there is no real, established process in most pharmaceutical companies yet; the majority of sponsors think about developing a risk strategy much too late and end up in crisis planning mode. REMS should be strategized in Phase II and planned during Phase III; it should not wait until clinical studies are completed and regulatory documentation is being developed. In time, the industry will turn to risk management planning sooner.

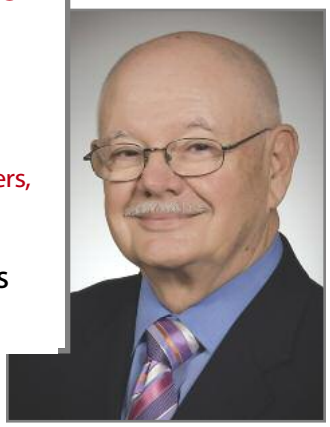
LEVINS. CCC. Start early, that's my advice; begin discussing risks in the preclinical phase. Also, think long term; all REMS programs must include a timetable for assessments, with assessments at 18 months, three years, and seven years after approval of the REMS — this is how the FDA checks that the REMS is actually working. Involve communication experts. To date, communications pros have not been squarely integrated into REMS planning teams. This is not productive because REMS are essentially communications programs at the very highest level. Risk information must be understood, resulting in safer use outcomes. Corporate communications, marketing communications, and other messaging veterans should be invited to the strategic planning table when REMS are being designed. Lastly, implementation and follow-up are entirely the manufacturer's responsibility. Communication with all company employees involved in drug marketing, especially the field salesforce, is vital.

PROVOST. INC Research. Early and continuous risk assessment and mitigation planning will help ensure the most complete understanding of a product's potential risks and enable a well-conceived REMS to be developed if the need for one arises. Ensure that a multidisciplinary team is engaged in the REMS process — epidemiology, safety, R&D, brand management, regulatory, and legal will all play important roles in a plan's development. Sponsors need to be proactive in their REMS discussions with the FDA. Avoiding early discussions of how potential safety signals will be addressed can cause unnecessary delays once a product is under formal review.

SCHNOLL. Pinney. REMS differ between and within therapeutic classes based on the results of the benefit-risk assessment of the product. The indication, patient population, seriousness of risks, setting for drug dispensing and administration, and other available treatment options all determine a REMS strategy. A

"When designing a REMS, sponsors should avoid introducing unnecessary barriers, or even perceived barriers, to medication access."

DR. EDGAR ADAMS
Covance



REMS should be devised during the drug's development to ensure the approval process is streamlined and not hindered.

DAVIS. United BioSource Corp. Once a REMS is decided upon, then its development can begin. It is important to know that the FDA has not yet provided detailed guidelines for REMS, so having knowledge of precedent programs is important. The first step is to decide which risk or risks should be addressed by the minimization strategy. The REMS should focus only on those risks for which the company believes added intervention over and above professional labeling and good pharmacovigilance is needed to minimize and assess that risk. The second step is to develop the goals and objectives of the REMS. These will vary depending on the scope and complexity of the plan and may include educational objectives to make sure that prescribers or patients are aware of particular risks. The third step is to decide on the best overall strategy for risk minimization. It is important to choose a customized strategy that will be sufficient to minimize the risk, while still allowing the best access to the product for appropriate patients and being the least burdensome to the healthcare system. The final step is to design an appropriate evaluation plan for the REMS. This basic approach applies regardless of the therapeutic category.

TROMBETTA. Saint Joseph's University. Now that the industry has caught on to the newer REMS legislation, there are an army of consultants and a host of seminars all designed to help sponsors design a REMS program. However, I don't think the challenge is knowing or not knowing how to design a REMS program; the key to a REMS program is that it's going to be 99% strategy and marketing, and not so much about the FDA or legal. In fact, there may be a need for sponsors to use a strategy called "demarketing," which means companies would downplay or defuse the use of the brand, especially in the case of a REMS requiring the product to be administered to a small, targeted patient population. What a REMS program needs to do is make sure the drug gets to only the people who should be using it and that the communication plan guides the physician to use the drug properly. Of course, this will upset the applecart in sales because how does a company compensate its salesforce for selling less? On the other hand, if a physician has to follow the steps of a REMS, now the sales rep has some value to bring to the table by offering to help him or her comply with the REMS. ✦

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Sound Bites From The Field

PHARMAVOICE POLLED LEADERS FROM DIFFERENT SECTORS OF THE INDUSTRY REGARDING WHAT THEY ARE DOING TO PREPARE FOR THE POSSIBILITY OF MORE DRUGS NEEDING A REMS PROGRAM.

JAMES MACDONELL is VP and Head of Delivery, Patni Life Sciences, a global provider of IT services and business solutions. For more information, visit patni.com.

"Comprehensive REMS require life-sciences companies to take a proactive approach to risk engineering throughout the product development process. Integrating comprehensive risk analysis and mitigation into all drug development activities, from molecular design through postmarketing surveillance, is needed to meet REMS. Reactive risk management will no longer be acceptable to regulatory agencies, patients, or shareholders. The costs, both monetary and goodwill, of not proactively planning and executing REMS will soon prove prohibitive. Gambling the company's future on reactive safety programs, late in product development without established, integrated risk management programs, is a formula for disaster."

JENNIFER RITER is Director of Sales for Analytical Services and Emerging Biotech Markets at West Pharmaceutical Services, a global manufacturer of components and systems for injectable drug delivery. For more information, visit westpharma.com.

"A prudent risk management program for drug product developers should include a comprehensive extractables and leachables testing program. A testing program can help reduce exposure to regulatory and product-related risks. The testing program should encompass the devices and system components that will be used to package and administer the drug products. By working closely with their component suppliers from the earliest stages of drug development, pharmaceutical and biopharmaceutical companies can select components that are appropriate for their intended use and that will help maintain the integrity of their drug over its shelf life."

UWE TIGÖR, M.D., is Senior VP and Director of Medical Strategy at Palio, a full-spectrum global pharmaceutical and consumer advertising, marketing, and communications agency. For more information, visit palio.com.

"The 2007 FDA Amendment Act broke with a long congressional record of easing the market introduction of new medications. Safety tops the current FDA agenda. If faced with a REMS mandate, I would encourage brand managers to view it as a necessary element of life-cycle management. Like every new tool, it will take the FDA time to calibrate the scope of its implementation. Coming out of 2008, many REMS programs are up already. Sponsors should compare previous scenarios and negotiate their REMS proactively. We also recommend using the REMS timetable wisely. FDA can eliminate assessments after three years if the compound's risks are adequately identified and managed."

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BY ROBIN ROBINSON

Preparation is key to preventing REMS from slowing time to market

REMS affects every sector of the industry, and good communications and planning are crucial to avoiding delays.

THE EARLIER THE BETTER

OUR EXPERTS SAY A WELL-PLANNED AND WELL-DESIGNED REMS CAN ONLY ENHANCE THE DRUG APPROVAL PROCESS. OUR REMS FORUM PARTICIPANTS DISCUSS THE NEED FOR BREAKING DOWN THE SILOS AND EARLY PLANNING TO ENSURE A TIMELY AND SUCCESSFUL REMS OUTCOME.

SIDNEY H. SCHNOLL, M.D., PH.D. PinneyAssociates. REMS should be considered as part of the drug-development process. The March 2005 guidances issued by the FDA emphasize the importance of incorporating risk management from the preclinical phase to the clinical phase, including risk assessment and developing risk mitigation strategies. When risk management is part of the drug-development process, all the necessary elements for a REMS will be predetermined and can then be included in the NDA. Therefore, REMS should not impede the approval process if risk management has been part of the development process from the beginning, and it should enhance the likelihood of approval.

DAVE PROVOST. INC Research. The core of the matter is whether proactive risk assessment and mitigation planning have been ongoing throughout a product's development. If they have, then it is likely that a well-conceived REMS has been developed and can be presented to the FDA to streamline the review and approval process. If ongoing risk evaluation has not been conducted, however, a company will likely not be in a position to respond quickly to FDA questions and concerns about product safety. In such a scenario, lengthy delays are very likely.

REKHA GARG, M.D. Amgen. The current REMS trends seem to indicate that there can be delays in the approvals of new compounds requiring REMS. There may also be a delay in approval of REMS for marketed products between the time the program was required for new safety information and approval of the strategy. The delay appears to be primarily related to the development, review, and approval of the REMS documents along with all the associated tools. A sponsor can try to anticipate and proactively design a REMS, but any REMS requirement beyond a medication guide may lead to additional time for approval.

WHEN THE NEW REMS PASSED INTO LAW, MANY IN THE INDUSTRY FEARED THE MANDATED PROGRAMS COULD DELAY THE DRUG APPROVAL PROCESS.

BREAKING DOWN THE SILOS

REMS IS A CROSS-FUNCTIONAL SPORT THAT WILL AFFECT EVERY SECTOR OF THE INDUSTRY.

EDGAR ADAMS, DR.SC., M.S. Covance. REMS is going to impact all phases of drug development, including marketing, clinical, and sales, but the greatest impact will be in the preclinical area. If companies know that there might be a mandated risk requirement at the end of the tunnel, they may try to identify safety signals earlier. If a drug is going to be pulled, it should fail fast, so the company doesn't spend $800 million on a drug that is not going to make it to market.

REKHA GARG, M.D. Amgen. REMS affects each sector of the industry, and the impact depends on the elements that are required for any given program. For example, if a REMS requires a medication guide only, then pharmacists and/or physicians are required to provide the medication guide to the patients per regulation. If a REMS requires special training for prescribers, then the sales staff would be required to educate prescribers on the product and its associated risk and document the training.

ILYSSA LEVINS. CCC. Internal stakeholders need to work hand in hand to effectively define and act on critical points for risk management. REMS is not just the responsibility of one functional area; diverse internal teams must collaborate along the entire REMS continuum to be effective. For companies that operate in silos, this represents a major challenge. Global executives must actively communicate across cross-functional teams to manage risk throughout all drug development phases. In this way, companies will become more sensitive to the implications of early planning on drug approval/marketing — cause and effect — engage in more effective long-term planning for product development and approvals, and be able to agree on sustainable process improvement. Sponsors shouldn't exclude their agency partners, who need to be part of relevant discussions.

DAVE PROVOST. INC Research. A REMS is not any one group's responsibility. The evaluation of product risks and how such risks can be avoided or minimized is a process that should begin early in a product's development and be top of mind throughout. All groups that touch a product — R&D, safety, regulatory, brand management, sales — need to be aware of a product's risks and need to contribute to help minimize them. The development team needs to consider study designs that can help provide insights into potential risks. The marketing team needs to understand a product's potential risks and the approved REMS elements to help ensure that the product's messaging clearly communicates its risk-benefit profile. The sales team needs to ensure it reinforces the proper use of a product and stays within its REMS so as not to send mixed signals to the physician community. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

APPROVED RISK EVALUATION AND MITIGATION STRATEGIES

NAME	DATE REMS APPROVED	(ALL REMS INCLUDE TIMETABLE FOR ASSESSMENT) REMS COMPONENTS	MARKETER
Actoplus Met XR (pioglitazone and metformin) Extended-Release Tablets	5/12/2009	Medication guide	Takeda Pharmaceuticals North America Inc.
Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder)	4/30/2008	Medication guide	GlaxoSmithKline
Advair HFA (fluticasone propionate and salmeterol xinafoate inhalation powder)	7/31/2008	Medication guide	GlaxoSmithKline
Aplenzin (buproprion hydrobromide) Extended-Release Tablets	4/23/2008	Medication guide	Sanofi Aventis
Avandamet (rosiglitazone maleate and metformin hydrochloride) Tablets	12/2/2008	Medication guide	GlaxoSmithKline
Avandaryl (rosiglitazone maleate and glimepiride) Tablets	12/2/2008	Medication guide	GlaxoSmithKline
Avelox (moxifloxacin) Tablets and I.V. Solution	4/27/2009	Medication guide	Bayer HealthCare
Banzel (rufinamide) Tablets	11/14/2008	Medication guide	Eisai Inc.
Cimzia (certolizumab pegol) Lyophilized powder for solution for subcutaneous injection	modified 12/31/2008 and 5/13/2009	Medication guide, communication plan	UCB Inc.
Cipro (ciprofloxacin) Tablets, Oral Suspension, I.V. Solution, and Extended-Release Tablets	4/27/2009	Medication guide	Bayer HealthCare
Creon (pancrelipase) Delayed-Release Capsules	4/30/2009	Medication guide	Solvay Pharmaceuticals
Dysport (abobotulinumtoxinA) Injection	4/29/2009	Medication guide, communication plan	Tercica Inc., an affiliate of the Ipsen Group
Edluar (zolpidem tartrate) Sublingual Tablets	3/13/2009	Medication guide	Orexo
Effient (prasugrel) Tablets	7/10/2009	Medication guide, communication plan	Eli Lilly
Enbrel (etanercept) for Subcutaneous Injection	6/23/2008	Medication guide	Amgen and Wyeth Pharmaceuticals
Entereg (alvimopan) Capsules	modified 2/5/2009	Communication plan, elements to assure safe use, implementation system	Adolor Corp. and GlaxoSmithKline
Epzicom (abacavir sulfate and lamivudine) Tablets	3/9/2009	Medication guide	GlaxoSmithKline
Factive (gemifloxacin) Tablets	4/27/2009	Medication guide	Oscient Pharmaceuticals
Forteo (teriparatide [rDNA origin]) Injection	7/22/2009	Medication guide, communication plan	Eli Lilly and Co.
Intron A (interferon alfa-2a)	5/2/2008	Medication guide	Schering-Plough
Kaletra (lopinavir and ritonavir) Oral Solution	4/6/2009	Medication guide	Abbott
Keppra, Keppra XR (levetiracetam) Tablets, Extended-Release Tablets, Oral Solution, and Injection	4/23/2009	Medication guide	UCB Inc.
Lamictal (lamotrigine) Tablets, Chewable Dispersible Tablets, Orally Disintegrating Tablets (ODT), and Extended-Release Tablets (XR)	4/23/2009, 5/8/2009, 5/29/2009	Medication guide	GlaxoSmithKline
Letairis (ambrisentan) Tablets	5/29/2009	Medication guide, elements to assure safe use	Gilead
Levaquin (levofloxacin) Tablets, Injection, and Oral Solution	4/27/2009	Medication guide	Ortho-McNeil-Janssen Pharmaceuticals
Lyrica (pregabalin) Capsules	4/23/2009	Medication guide	Pfizer
Noroxin (norfloxacin) Tablets	4/27/2009	Medication guide	Merck
Nplate (romiplostim) for Subcutaneous Injection	8/22/2008	Medication guide, communication plan, elements to assure safe use, implementation system	Amgen Inc.

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▶ APPROVED RISK EVALUATION AND MITIGATION STRATEGIES

NAME	DATE REMS APPROVED	(ALL REMS INCLUDE TIMETABLE FOR ASSESSMENT) REMS COMPONENTS	MARKETER
Onsolis (fentanyl buccal soluble film)	7/16/2009	Medication guide, communication plan, elements to assure safe use, implementation system	BioDelivery Sciences International Inc.
Pegasys (peginterferon alfa-2a)	Modified 4/20/2009	Medication guide	Roche
PegIntron (peginterferon alfa-2b)	12/11/2008	Medication guide	Schering-Plough
PegIntron Rebetol Combopack (Peginterferon alfa-2b, Redipen Single-dose Delivery System and Rebetol Ribavirin)	6/13/2008	Medication guide	Schering-Plough
Promacta (eltrombopag) Tablets	11/20/2008	Medication guide, elements to assure safe use, implementation system	GlaxoSmithKline
Proquin XR (ciprofloxacin) Extended-Release Tablets	4/27/2009	Medication guide	Depomed
Rozerem (ramelteon) Tablets	10/20/2008	Medication guide	Takeda Pharmaceuticals North America Inc.
Savella (milnacipran hydrochloride) Tablets	1/14/2009	Medication guide	Forest Pharmaceuticals
Simponi (golimumab) Injection	4/24/2009	Medication guide, communication plan	Centocor Ortho Biotech/Schering-Plough
Sucraid (sacrosidase) Oral Solution	11/20/2008	Communication plan, elements to assure safe use, implementation system	QOL Medical Inc.
Symbicort (budesonide and formoterol) Inhalation Aerosol	2/27/2009	Medication gude	AstraZeneca
Symbyax (olanzapine and fluoxetine) Capsules	3/19/2009	Medication guide	Eli Lilly and Co.
Tapentadol Tablets	11/20/2008	Medication guide	Johnson & Johnson
Topamax (topiramate) Tablets and Sprinkle Capsules	4/23/2009	Medication guide	Ortho-McNeil
Treximet (sumatriptan succinate and naproxen sodium) Tablets	4/15/2008	Medication guide	GlaxoSmithKline
Trilipix (fenofibric acid) Delayed-Release Capsules	12/15/2008	Medication guide	Abbott Laboratories and Solvay Pharmaceuticals
Trizivir (abacavir sulfate, lamivudine, and zidovudine)	3/9/2009	medication guide	GlaxoSmithKline
Tyzeka (telbivudine) Oral Solution	4/28/2009	Medication guide	Novartis Pharmaceuticals Corp.
Tyzeka (telbivudine) Tablets	1/23/2009	Medication guide	Novartis Pharmaceuticals Corp.
Venlafaxine hydrochloride Extended-Release Tablets	5/20/2008	Medication guide	Osmotica Pharmaceutical Corp.
Vimpat (lacosamide) Injection	10/28/2008	Medication guide	UCB Inc.
Viramune (nevirapine) Tablets and Oral Suspension	6/24/2008	Medication guide	Boehringer Ingelheim
Xenazine (tetrabenazine) Tablets	8/15/2008	Medication guide, communication plan	Lundbeck Inc.
Ziagen (abacavir sulfate) Tablets and Oral Solution	7/18/2008	Medication guide	GlaxoSmithKline
Zolpimist (zolpidem tartrate) Oral Spray	12/19/2008	Medication guide	NovaDel Pharma
Zonegran (zonisamide) Capsules	4/23/2009	Medication guide	Eisai Inc.
Zyprexa, Zyprexa Zydis (olanzapine) Tablets	3/19/2009	Medication guide	Eli Lilly and Co.

Source: FDA. For more information, including application type, date approved, and REMs components, visit fda.gov.
Note: List was last updated July 23, 2009.

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DATE AND TIME

Wed., Sept. 30, 2009
12 PM - 1 PM ET

GUEST SPEAKERS

Lee Blansett
Senior Vice President
Oncology Market Access
MattsonJack

Dr. Susanne Michel MD, MSc
Head of Global Market Access,
Pricing and Reimbursement
TNS Healthcare

FEATURING

New Research on Public Reactions to the Proposed Obama Reforms

The pharmaceutical and biotechnology industry is confronting significant short-term and long-term challenges. Financial pressures from current generic competition, upcoming patent expirations, and pending healthcare legislation and reforms in both the US and EU, are forcing the industry to "rethink" everything from R&D to Marketing. Future revenue growth in the US and EU is unclear, so pharma and biotech companies are looking to Emerging Market opportunities in Brazil, Russia, India, and China (i.e., BRIC) to drive future business. The EU is wrestling with the cost effectiveness of treatments and working through key changes in important regulatory processes. In addition, US healthcare reforms and pending legislation are pointing to universal coverage or the emergence of a "national plan."

What does this all mean for patients, physicians, payers, and pharmaceutical / biotech manufacturers especially as payer actions and priorities converge across borders?

KEY TAKE-AWAYS:

- Guidance on Creating Effective Access Strategies for the High-Growth Emerging Markets
- Critical Developments Influencing US Market Access for High Cost Drugs: The Strategic Implications for Pharma and Biotech
- Insights Into New Trends for Financing Healthcare (Including Specific Country Examples Showing Key Changes in Health Systems and Regulatory Processes)
- The Growing Focus on Cost Effectiveness in the EU: The Impact on Future Branding and Pricing Strategy
- Understand How to Identify and Impact Decision Makers at Every Level – National, Regional, and Individual Insurer
- How and Why EU Healthcare Initiatives Can Better Inform the Debate on US Healthcare Reform

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