Trends-in-Medicine

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SUMMARY

AstraZeneca's Exanta will fill a niche, but it won't replace warfarin – it's too expensive. ♦ GlaxoSmithKline's Wellbutrin XL is quickly replacing Wellbutrin SR but not expanding Wellbutrin use . ♦ Forest's Lexapro is replacing Celexa, but generic citalopram could be a spoiler for Lexapro. ♦ Cephalon has a big sell-job ahead to convince family doctors to prescribe Provigil for excessive daytime sleepiness, especially without a sleep lab study. ♦ Family doctors are not convinced that Wyeth's low-dose Prempro is safer than regular Prempro, and it won't reverse the decline in Prempro use. ♦ AstraZeneca's Crestor is likely to do well with family medicine doctors, who have no safety concerns about it. ♦ Use of Schering Plough's Zetia is expected to more than double over the next year. ♦ If Dr Reddy/Par's amlodipine maleate is priced lower than Novartis's Norvasc, it will take market share even without an A/B rating. ♦ Few doctors are prescribing Watson's Oxytrol, but they expect use to pickup. ♦ There is little interest in MedImmune's FluMist, with cost the biggest – but not the only -- problem. ♦ P&G's Prilosec OTC is catching on – with patients, doctors and managed care – but doctors are still writing brand prescriptions, though they expect that to get more difficult. HMOs are starting to require that patients take an OTC first and then a generic before a brand.

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THE FAMILY MEDICINE PERSPECTIVE

Family medicine doctors often write more prescriptions for particular medicines than their specialist counterparts, so understanding their attitudes toward a variety of topics and their clinical practices are very important in determining the outlook for new drugs and devices as well as expanded labels for existing products. At the American Academy of Family Practitioners annual meeting in New Orleans from October 1-4, 2003, 72 doctors were questioned on an eclectic mix of topics, from Alzheimer's Disease to anticoagulation, antidepressants, diabetes, excessive daytime sleepiness, HRT, hyperlipidemia, hypertension, incontinence, flu, IT, and PPIs.

NOTE: The American Academy of Family Physicians (AAFP) is changing its name to the American Academy of Family Medicine, and these primary care doctors now prefer to be called family medicine physicians, not practitioners.

Cost of medications has become a huge issue with these doctors and their patients, and that is expected to have significant impact on their willingness to use new drugs. HMOs also are becoming more restrictive, particular with formularies but also in other areas. A Virginia doctor said, "Formularies certainly have gotten more restrictive. Some HMOs went to point-of-service, allowing patients to choose their physicians, but the cost to the patient is high because the doctor gets paid less and can charge the patient more." A Pennsylvania doctor said, "Formularies, in particular, have gotten more restrictive, but, on the other hand, a lot of HMOs are doing away with limits on referrals, tests and consults." A Wisconsin doctor said, "HMOs have gotten more restrictive across the board. Even my own insurance and my own co-pays have gone way up." A Maine doctor said, "HMOs are having more and more impact, and patients are having less and less choice because the cost of brands puts the medications out of the reach of many patients." A Minnesota doctor said, "The latest thing is that HMOs won't cover any non-sedating antihistamine because Claritin went over-the-counter."

In alphabetical order these topics are:

ALZHEIMER'S DISEASE (AD)

Half the 14 doctors questioned on this topic said they treat AD, but only three were aware of Forest Laboratories's Namenda (memantine). None reported any pent-up patient demand for Namenda. However, many believe it will find significant use. A Kansas doctor said, "An add-on medication will have a good place. Off-label use in earlier disease is likely if the safety is okay. The only limit on use will be cost." Another doctor said, "I think Namenda will be big. Current medications are not 100% effective. If there is a possibility of slowing progression, then I will use it off-label earlier. Families are so desperate." An Idaho doctor said, "I'll try not to use it off-label in earlier disease for six to 12 months after approval."

ANTICOAGULATION

Getting patients on warfarin -- Bristol-Myers Squibb's Coumadin or generic warfarin – can be gotten to their INR goal. It is not always easy, but it generally can be done, 10 sources agreed. An Oklahoma doctor said, "Most patients get to goal. It's not that hard, but we've had some compliance problems after they get there." An Ohio doctor said, "I can't remember the last patient who didn't get to the INR goal." A Louisiana doctor said, "For most patients, it is not a problem. It is more a pain in the neck for patients than doctors." A Texas doctor said, "It is tedious but not difficult." A Wisconsin doctor said, "You can get everyone there, but it takes a lot of adjustment and depends on their diet, size, etc. I've never had a patient I couldn't get to goal." An Illinois doctor said, "We have a Coumadin clinic run by the nursing staff…Coumadin is never an easy drug to manage, but we get all patients to goal eventually. Keeping them there is the problem."

Doctors estimated that, on average, only 8% of their patients don't get to goal. A New York doctor said, "Seventy percent get in range. I'm not sure why the others don't; sometimes they skip doses or take it at the wrong time." A Louisiana doctor said, "Only about 5% of our patients don't get to goal, and alcohol use is the biggest reason." A Montana doctor said, "There is a small group – 10% -- who are very difficult to get to goal. They are the frail elderly, middle aged men who like an afternoon cocktail, etc. So, it depends on lifestyle, BMI, etc." A New Jersey doctor said, "For 75% of patients it is a no-brainer, but 25% are very difficult to control – because of diet, lack of compliance, medication interactions, etc."

Monitoring patients on warfarin isn't a problem for doctors, but it can be a nuisance for patients. A Texas doctor said, "It is burdensome for patients but not doctors." A New York doctor said, "It is not a big deal for me, but it may be stressful for the patient." An Illinois doctor said, "Monitoring means 15 extra office visits a year for the typical patient." An Oklahoma doctor said, "It is not onerous. Nurses can go to the patient's home if that is an issue." A Louisiana doctor said, "It is easier now because there are home testing kits that are especially useful for patients who live far from the office." A Montana doctor said, "When patients find out how simple and critical the monitoring is, they do it." A New Jersey doctor said, "Monitoring is fairly easy if you have good clinical methods in the office. We have EMRs which helps us remind patients and quickly process results. Monitoring is more work for manual offices."

The pool of patients not being treated with warfarin who could benefit from treatment is relatively small – on average 10% of patients – and often this is **not** due to problems with monitoring. An Ohio doctor said, "Maybe 25% of patients aren't getting warfarin who could benefit, but they are mostly really old people where we worry about falls." A Texas doctor said, "About 20% of warfarin patients drop out, but a lot of times that is based on disabilities, co-morbidities and the fall risk." A Wisconsin doctor said, "Less than 5% of patients don't take warfarin who should, but there are patients who just don't feel good on warfarin or are worried about falls." A Montana doctor said, "There are a few people who refuse warfarin, and some who have a high risk of fall."

Thus, these doctors predicted that newer agents, such as **AstraZeneca's Exanta** (ximelagatran), will have a niche, but won't find widespread use because of their expected higher cost. An Oklahoma doctor said, "Exanta will have a good niche, but it won't replace warfarin." An Ohio doctor said, "Some patients will want Exanta, but the cost will be an issue." An Illinois doctor said, "The cost of monitoring adds up, but Medicare pays for monitoring and not for pills. Some patients will prefer Exanta, but the questions will be the cost and who pays." A New York doctor said, "I wouldn't switch patients (from Coumadin to Exanta), given the cost – unless there were benefits other than convenience. Warfarin is fine." A Texas doctor said, "The cost of the new drug vs. the monitoring cost will be something for families to weigh." A Wisconsin doctor said, "We have tons of warfarin patients, and they don't have the budget for new anticoagulants. It would be great not to monitor, but cost is a big issue. The cost of monitoring is less than the cost of new drugs. And some older patients like the attention they get with warfarin monitoring." A Louisiana doctor said, "If Exanta is more convenient, then usage will depend on managed care coverage. If there is less monitoring, managed care may like it, and patients would love to do with fewer blood tests."

ANTIDEPRESSANTS

Eleven of 13 doctors questioned said they prescribe Wyeth's Effexor (venlafaxine). On average, they currently use Effexor for 7% of patients on an antidepressant.

Sources all praised **GlaxoSmithKline's Wellbutrin XL** (buproprion). A Texas doctor summed up the feeling: "Everyone likes it better (than Glaxo's Wellbutrin SR)." However, most sources (8 of 13) said Wellbutrin XL will not expand their use of Wellbutrin. Another doctor said, "XL is just a more convenient form of Wellbutrin."

For new patients, doctors are split on which formulation of Wellbutrin to use first. Half plan to continue prescribing Wellbutrin SR for new Wellbutrin patients, and half will use Wellbutrin XL first. An Oregon doctor said, "I'll start with SR first." Another said, "I don't want to start with XL because it is such a strong dose."

Forest appears to be doing a good job of converting family medicine doctors from **Celexa** (citalopram) to its next-generation product, **Lexapro** (escitalopram). Most sources are using Celexa and Lexapro equally, though a few are using Lexapro more frequently, and a few are using Celexa more frequently. Only one source is not using Lexapro. And most

doctors predicted that Lexapro use will increase over the next six to 12 months, with Celexa use declining.

The impact of a generic citalopram will depend on what formularies do. An Alabama doctor said, "The generic may affect Lexapro as well as Celexa because of cost." A Minnesota doctor said, "It depends on co-pays and formularies. Only a small percentage of patients pay for their medications." Another doctor said, "Some formularies will require the generic." A California doctor said, "Part of it is formulary-driven, and the rest is cost. Cost is the bottom line."

DIABETES

The eleven doctors questioned about oral diabetes medications said they use **Lilly's Actos** (pioglitazone) for an average of 55% of their Type 2 diabetic patients on a glitazone, and **GlaxoSmithKline's Avandia** for 45%. None have seen any recent shifts in usage between the two drugs, and none expect a shift in the near future. There is little excitement about – or knowledge of -- drugs in the pipeline.

EXCESSIVE DAYTIME SLEEPINESS

Every doctor questioned about **Cephalon's Provigil** (modafanil) was familiar with it as a treatment for narcolepsy. In late September, an FDA Advisory Panel voted to recommend a label expansion for Provigil to include treatment of excessive sleepiness associated with disorders of sleep and wakefulness, such as shift work sleep disorder. However, sleep specialists were concerned that a broadened label might encourage primary care physicians to prescribe Provigil instead of sending patients to a sleep lab first for an evaluation.

Family medicine doctors were questioned at the AAFP meeting about how they expect to use Provigil if it gets an expanded label. None currently are prescribing Provigil off label for sleepiness not associated with narcolepsy, and most insisted that they would take a conservative approach to any label expansion. They also said they will continue to send patients to the sleep lab for evaluation. A New York doctor said, "Most shift workers try to get by on bits and pieces of sleep, and I try to work on other means of longer sleep, rather than giving something to keep them awake." A Virginia doctor said, "I'll use Provigil but only after a sleep lab evaluation. The typical shift worker will ***not*** want to do a sleep lab, but I insist." An Ohio doctor said, "Most of my patients will go to the sleep lab first, but some might warrant a trial of Provigil first, given the cost of the sleep lab…Provigil might be good for chronic pain patients who are experiencing sedation." A Texas doctor said, "Once people make a shift change, they adjust, but Provigil might be useful for people who change shifts or a frequent shift jumper – but only after a sleep lab."

HORMONE REPLACEMENT THERAPY (HRT)

In the wake of the negative news about HRT from the Women's Health Initiative, family medicine doctors and their patients have little interest in **Wyeth's Prempro** -- a fixed-dose combination of 0.625 mg Premarin (conjugated equine estrogen, CE) and 2.5 mg Cycrin (medroxyprogesterone acetate, MPA). A new low-dose formulation of Prempro (0.3 mg CE and 1.5 mg MPA) is not getting a very warm reception, and doctors said it is unlikely to reverse the decline in Prempro usage. An Ohio doctor said, "There is no patient demand for low-dose Prempro, and I won't encourage (menopausal) patients to use it unless they are symptomatic and worried about the symptoms or are disabled by the symptoms." Another Midwest doctor said, "Low-dose Prempro is a way to help a woman manage hot flashes. Personally, I want an estrogen-alone product, not a combination with progestin in it." A Virginia doctor said, "Low-dose Prempro may be useful for women who stopped Prempro due to the negative press but are feeling bad. They may come back and start the new, low dose version…But I haven't decided yet how to use it." An Arizona doctor said, "Low-dose Prempro may make patients feel more comfortable, but I'm not sure I agree with them. If Prempro is not safe, then lowering the dose doesn't make me comfortable." A Maryland doctor said, "A lot of patients would rather take the lowest possible dose, and I would rather prescribe the lowest possible dose. If that doesn't work, then I will increase the dose."

HYPERLIPIDEMIA

ASTRAZENECA'S Crestor (rosuvastatin)

AstraZeneca made a big push for its new statin, Crestor at the meeting. There was a fairly large theater-style area at the AstraZeneca booth, where expert lectures were offered several times a day, and these were well attended. Nine of 10 doctors questioned about Crestor were familiar with it, even though only four of these had been detailed on it yet. A California doctor said, "I'll be detailed next week." An Ohio doctor said, "I haven't been detailed, but I've read about it." A New York doctor said, "I haven't been detailed, but I've see a lot of ads."

None of these sources has any safety concerns about Crestor, and none had heard any negative counter-marketing about Crestor. In fact, a few believe Crestor actually is safer than other statins. A Midwest doctor said, "Crestor seems pretty good, with less muscle side effects than the other statins." Colorado doctor said, "I think it is comparable to other statins." A Maryland doctor said, "I read in ***Prescriber's Letter*** that it is the same as the other statins. I'm not aware of any safety concerns." A Texas doctor said, "Crestor is as safe as other statins."

Seven of these 10 doctors plan to prescribe Crestor. On average, they predicted that Crestor would account for 13% of their statin prescriptions within a year. A Texas doctor said, "Because of its pathway, I'm inclined to use Crestor more in people that I can't get to goal with cost-effective doses of another statin." A Colorado doctor said, "I'll use it like the other statins." A Maryland doctor said, "I use all the statins about equally, and I'll probably use Crestor, too, unless I hear about a safety issue."

The three doctors who do not plan to prescribe Crestor had different reasons. One said it is not yet on his the military formulary. Another prefers Pfizer's Lipitor (atorvastatin) and Merck's Zocor (simvastatin), noting that there is outcomes data on Zocor and not Crestor, but concluding, "They are all probably the same." A New York doctor said, "I won't be the first – or the last – to use Crestor. I'm waiting for ***The Medical Letter*** to discuss it. But one of the reasons I'm here at AAFP is to learn more about what's new in treating hyperlipidemia." Another doctor said, "A new product will take a while to catch on because the other medications work well."

Crestor is expected to take market share primarily from Lipitor. A source said, "Lipitor will be hurt the most because Crestor is a superstatin." A Texas doctor said, "I use mostly Lipitor and Zocor, and that's what will be hurt." An Ohio doctor said, "I use mostly Lipitor, so that's who will be hurt."

SCHERING PLOUGH'S Zetia (ezitimibe)

Half the doctors (6 of 12) asked about Zetia said they have started prescribing it. A Kansas doctor said, "I use it mostly in combination with a satin, usually Lipitor or pravastatin (Bristol-Myers Squibb's Pravachol)." A Texas doctor said, "I use it for patients who don't tolerate statins, mostly as monotherapy." A Colorado doctor said, "I use Zetia occasionally as add-on therapy when a patient is not adequately controlled, but that is unusual for me." An Arizona doctor said, "I use it for elevated LDL, usually as an add-on with any statin, but most commonly with pravastatin.. However, it is insignificant in the grand scheme of things, a niche product." An Ohio doctor said, "Twenty percent of my patients are already on Zetia. I use it before a statin. A large percentage of patients don't need the power and side effects of statins."

Three doctors were unfamiliar with Zetia, and three said it is not on their formularies. None of these doctors plan to start using it.

On average, Zetia currently is being prescribed to 4% of these doctors' hyperlipidemia patients. In a year, doctors predicted that would more than double to an average of 9%. Zetia is impacting use of all statins somewhat, but Lipitor the most, sources indicated. A Texas doctor said, "I give Zetia to about 5% of my (hyperlipidemia) patients now, and I expect that to go up to 5%-10%. The news will be when the combination of Zocor and Zetia is available." A Colorado doctor said, "My Zetia use is minimal and I don't expect that to change." An Arizona doctor said, "My use will be flat."

HYPERTENSION

Angiotensin II Receptor Blockers (ARBs)

Most sources said they have no preference among the seven approved ARBs, and many use them all:

- AstraZeneca's Atacand (candesartan)
- Biovail's Teveten (eprosartan)
- Boehringer Ingelheim/Abbott's Micardis (telmisartan).
- Bristol-Myers Squibb's Avapro (irbesartan)
- Merck's Cozaar (losartan)
- Novartis's Diovan (valsartan)
- Sankyo/Forest Laboratories's Benicar (olmesartan)

Family doctors said that once they find an ARB that works well, there is a reluctance to change. A Nevada doctor said, "I use Cozaar because that's the hospital's preference." A Minnesota doctor said, "I use Diovan because it works." Another Midwest doctor said, "I prescribe whatever the cardiologists prefer." The exception was a Kansas doctor who said he currently is using Diovan and Benicar equally, but predicted Benicar use would increase: "Benicar is just getting going. If it works, then use will go up at the expense of Diovan."

Calcium Channel Blockers (CCBs)

Chronotherapy appears to have little appeal to these sources, if the attitude of primary care doctors toward **Biovail's Cardizem LA** (diltiazem) is any indicator. Cardizem LA, a once-daily graded-release formulation of diltiazem HCl, was approved by the FDA earlier this year. It is labeled for administration in the morning or evening, but when dosed at night, it reaches peak in the morning, when patients are thought to be at the greatest risk of cardiac arrest.

Half the sources currently are prescribing Cardizem LA, but sources cited reasons other than chronotherapy for their use of this drug. Most of the doctors who don't use Cardizem LA said it is because their cardiology colleagues don't use or recommend it. A Kansas doctor said, "Cardizem LA definitely has a role in treatment, more because it is once-a-day than because it is chronotherapy. It isn't my drug of choice, and some of our decisions are directed by our cardiology." A Nevada doctor said, "I have several patients on Cardizem LA – diabetics who can't take lisinopril (AstraZeneca's Zestril), and patients who come to me on it from an employer health plan…It seems good, but it isn't my drug of choice."

Dr. Reddy/Par Pharmaceutical's amlodipine maleate, a variation of **Pfizer's Norvasc** (amlodipine besylate), is

awaiting FDA approval. Since it is a different salt, it probably won't be A/B rated, but it is expected to be priced at about a 20% discount to Norvasc. Family medicine doctors were asked how they would weigh the lack of A/B rating against the lower price – and price won out in most cases. A Pennsylvania doctor said, "I'll probably switch (from Norvasc to amlodipine maleate). A/B rating is less important than cost." A Wisconsin doctor said, "No A/B rating makes me cautious, but I won't avoid amlodipine maleate. I'm willing to try it in some patients, and if it works as well, I'll continue. But it won't get much use until I have my own experience with it."

Two doctors said they would take a slow approach to use of amlodipine maleate. A Virginia doctor commented, "Until there is more data, I prefer the brand. If two drugs are the same, I use the cheaper, but often two medications are not exactly the same." A Texas doctor said, "I use more Lotrel [Novartis's combination of Norvasc and Lotensin (benazepril)] than Norvasc. When generics first came out, I wrote a lot of generics, but I found a lot of them don't work as well as the brand."

Most sources pointed out that they are not big Norvasc users. A Nevada doctor said, "In this economy, price is the issue, but I try not to start Norvasc." A Midwest doctor said, "I don't use a lot of Norvasc because of the side effects, and CCBs are not the best – but the lack of an A/B rating is not an issue." A California doctor said, "I'm not a fan of Norvasc, and I don't write it…but price is more important to me than A/B rating."

INCONTINENCE

Virtually all of these doctors treat urge incontinence, with the rare exception of military or VA doctors who see only male patients, and they are very comfortable with patches, which they commonly prescribe for birth control and other uses. A Kansas doctor said, "I use a lot of patches for HRT and antihypertensives. Patches are catching on." An Ohio doctor said, "Patches are good, useful, and convenient." An Illinois doctor said, "Patches are a good idea. They have few side effects." An Idaho doctor said, "People either like or don't like patches. Most people get a skin rash and stop using patches."

Only three of 17 doctors asked about **Watson's Oxytrol** (transdermal oxybutynin) had been detailed about this patch yet, and only one has started prescribing it. Watson had a booth at AAFP, but it was not in a prominent place, and traffic appeared light. However, more than half these sources expect to start prescribing it soon, and, on average, they expect to have 7% of their overactive bladder patients on Oxytrol within a year. An Idaho doctor said, "Cost will be the biggest factor in my decision to use Oxytrol." A Kansas doctor said, "I can see using Oxytrol for 25% of my patients within a year." A Texas doctor said, "I may use Oxytrol, but it will probably be for less than 3% of my patients. It would be good for people on oral medications who like the drug but forget their pills or like the idea of a patch." A Virginia doctor said, "I need to learn more about Oxytrol, and then I will incorporate it into what I prescribe. But I need more than just detailing by a sales rep. I need to hear a lecture or see some tapes."

INFLUENZA

Five of 14 doctors questioned about flu prevention said they plan to use **MedImmune's FluMist**, a nasal spray flu vaccine, this flu season. One said, "It will be beneficial for children." An Illinois doctor said, "I will offer it, but a flu shot is covered by HMOs, and FluMist is not. It would be a good alternative (to the flu shot) if it were cheaper." A Kansas doctor said, "Some patients have asked for FluMist, so I will make it available, but I don't expect many patients to want it." A West Virginia doctor said, "I offer it. It's a good idea." A Mississippi doctor said, "I think it's great."

A speaker at a seminar on flu treatment said his audience was overwhelmingly negative about FluMist. He cited a number of reasons not to use FluMist, including:

- **Lack of data.** "FluMist has only been studied in 5-to-49-year olds. It is not approved for the patients who need it the most."
- **Live virus.** "Patients are contagious after receiving FluMist, so someone who gets it can't be near an immune-compromised person for three weeks."
- **Number needed to treat.** "You need to give FluMist to 35 people to prevent one upper respiratory infection (URI). You only need to give the intramuscular (IM) vaccine to 13 people to prevent one URI, so the IM is three times a effective in preventing URIs."
- **Allergies.** "FluMist is contraindicated in people with an egg allergy."
- **Dosing.** "You have to get two doses in the first year, and that increases the cost to $110 the first year."
- **Storage.** "FluMist has to be kept refrigerated until use, and it can't be stored long once reconstituted."
- **Pregnancy.** "FluMist can't be given to pregnant women, but the IM vaccine can."
- **Cost.** "FluMist is very, very expensive. It costs $34 a dose in the military, compared to $1.72 for the shot."

Cost is the over-riding reason for a lack of enthusiasm for FluMist among other doctors questioned at the meeting. Eleven of 15 described FluMist as "too expensive." A Texas doctor said, "FluMist is too expensive, and insurance doesn't pay well for it." A Massachusetts doctors said, "It is just too expensive." A Minnesota doctor said, "FluMist is too expensive. I'll stick with the shot." One doctor said, "It is not appropriate for the elderly, and that is most of my patients."

INFORMATION TECHNOLOGY (IT)

The doctors interviewed all agreed that there is value to IT systems, and many already have computerized their offices. A doctor said, "We are fully computerized, and it has been very valuable. It makes prescriptions and refills easier, but it is more time-consuming than hand-writing records." An Alabama doctor said, "I'm not computerized yet, but I see value in it. For me, it is a money issue." The business manager for a Missouri physician said, "We are a solo practice, and IT allowed us to hire a lot fewer employees…We opened in November 2002, and we can do our own billing, dictation, reports, etc. All the little expenses that add up are included. It helps us manage our practice better and educates us on what the practice is doing."

Is there a future for electronic medical records? The answer is: Definitely – but probably not for five to 10 years. A California doctor said, "We already have EMRs. It took a while for them to feel user-friendly, and it was easier for me than for my older partners. They still need to get more user-friendly, but it is cost-effective. The hospital has EMRs, too, but it is hard to get the specialists to use them." Another doctors aid, "Absolutely, there is a future. Some day the only record will be the EMR, but they need more revisions first. Wide use is probably 10 years away. Only 3% of practices are fully computerized We are, and it is not a plus because it costs us more than it saves us, but it was still the right thing to do. There are no lost charts, no misplaced charts. It is a quality step up but an efficiency step back. AAFP is working on an open-architecture EMR. The vendors don't like it, but it would be great because what do you do if your vendor goes out of business?" An Alabama doctor said, "I think EMRs will be common within the next five years." Another source said, "EMRs are great. We have that now, and it is totally cost effective."

PROTON PUMP INHIBITORS (PPIS)

Despite the availability of non-prescription **Proctor & Gamble's Prilosec OTC** (omeprazole) at the corner pharmacy, doctors are continuing to write prescriptions for brand name PPIs – AstraZeneca's Nexium (esomeprazole), TAP Pharmaceuticals' Prevacid (lansoprazole), Eisai/Johnson & Johnson's AcipHex (rabeprazole), and Wyeth's Protonix (pantoprazole). Five of the 10 doctors questioned about PPIs, said they are still writing prescriptions for brand PPIs. A Virginia doctor said, "By the time patients come to me, they've already tried OTC H2 blockers. Patients haven't caught on yet to Prilosec OTC, so I write a prescription." A Pennsylvania doctor said, "I will try to tell patients to try Prilosec OTC first, but they will want a prescription. It will be the same problem we had with antihistamines when they went over-the-counter. Suddenly patients will say the OTC doesn't work. Once all the PPIs are OTC, it will be a level playing field again." A Maine doctor said, "I write a prescription because insurance pays for that, and my patients can't afford Prilosec OTC." A Texas doctor said, "I still write only brand prescriptions." A Midwest doctor said, "I mostly write prescriptions because most patients will have tried Prilosec OTC before they come to me."

Five doctors are recommending OTC to some patients and writing prescriptions for other patients. A Wisconsin doctor said, 'I tell patients to see what is cheapest for them, and I do that." A Pennsylvania doctor said, "It depends on the insurance. I tell patients to try Prilosec OTC, but if the patient says it is cheaper to get a prescription, then I write that."

Among these doctors, when a brand is prescribed, it is most often Protonix, with one writing prescriptions mostly for Prevacid, and one writing only Nexium (because it works for him personally). The other doctors spread their use out fairly even among the brands.

However, most sources believe OTC use will increase – and at the expense of all the brand PPIs. A Maine doctor said, "I'm surprised that managed care still covers brands. I wouldn't be surprised to see all the brands yanked off formularies." A Wisconsin doctor said, "Lots of patients are switching to OTC instead of brands, with all brands affected."

Generic omeprazole has had little impact with these doctors yet – mostly because the cost savings haven't been there, they said. An Arkansas doctor said, "I've just started using generic omeprazole, and it will affect all the brands." A Pennsylvania doctor said, "There hasn't been any great impact yet from generic omeprazole, but I think the generics eventually will have an impact as the prices comes down." A Virginia doctor said, "Generic omeprazole is not a factor yet. It is too early to say how it will affect brands." A Kansas doctor said, "I bet they will all have to go OTC or lose market share."

In the future, though, generic omeprazole is likely to become a middle step between Prilosec OTC and brand PPIs. A Wisconsin doctor said, "I usually use samples, and then prescribe the sample if it works, but more formularies and HMOs are mandating generic omeprazole before a brand." A Maine doctor said, "I prescribe OTC first, then generic, then brand." A Pennsylvania doctor said, "HMOs are tiering these drugs: OTC first, then generic, and then brand."

Most managed care firms are not mandating Prilosec OTC, but they are making it harder to prescribe brand PPIs. A Midwest doctor said, "HMOs are saying patients can't get brands without trying generic first." A Virginia doctor said, "All brands are becoming Level 3 drugs, like the non-sedating antihistamines, which costs patients substantially more." A Pennsylvania doctor said, "Prior authorization is needed for anyone who is on a PPI for more than eight weeks. Some prior authorizations are really difficult to get. One HMO even wants an endoscopy done first – and the endoscopy report sent in!" An Arkansas doctor said, "Some HMOs are demanding Prilosec OTC first." A Wisconsin doctor said, "Most HMOs

are requiring generic omeprazole first." A Wisconsin doctor said, "Some HMOs demand OTC first, others are covering the usual preferred PPI, and some are demanding a generic before the brand."

Yet, there have been few formulary changes among the brand PPIs. A Wisconsin doctor said, "A couple of HMOs are talking about dropping Nexium for generic omeprazole." A Virginia doctor said, "There haven't been any changes because they are all Level 3 drugs now."

MISCELLANEOUS

ALLERGAN'S Botox (botulinum toxin A). No doctor was found who offers Botox or plans to do so.

Multiple Sclerosis. Family practice doctors help manage these patients, but the choice of medication is between the patient and the neurologist.

SOLVAY'S Aceon (perindopril). There wasn't even any signage at the Solvay booth about this ACE inhibitor or the EUROPA data, and it does not appear that Solvay is putting any serious marketing effort behind this drug. A source indicated that, with Aceon the 11th ACE inhibitor in a market that also has generics, Solvay just doesn't want to put many resources behind Aceon. Thus, it doesn't appear that Aceon will be a threat to King's Altace (ramipril).

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