THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Ron Graham, D.Ph.

SUBJECT: **Packet Contents for Board Meeting – January 11, 2005**

DATE: January 6, 2005

NOTE: **THE DUR BOARD WILL MEET AT 6:00 P.M.**

Enclosed are the following items related to the January meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – **See Appendix A.**

New Legislature Update and Budget Issues

Update on DUR/MCAU Program - **See Appendix B.**

Action Item – Update and Vote on Prior Authorization Status of Antidepressants – **See Appendix C.**

New Product Review - Cymbalta® - **See Appendix D.**

30 Day Notice of Intent to Prior Authorize Bladder Control Drugs - **See Appendix E.**

Annual Review of Anxiolytic / Hypnotic PBPA Category – **See Appendix F.**

30 Day Notice of Intent to Prior Authorize Lunesta® – **See Appendix G.**

Review and Discuss Multiple Sclerosis Medications - **See Appendix H.**

Annual Review of ADHD / Narcolepsy PBPA Category – **See Appendix I.**

FDA and DEA Updates – **See Appendix J.**

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – January 11, 2005 @ 6:00p.m.

Oklahoma Health Care Authority
4545 N. Lincoln Suite 124
Oklahoma City, Oklahoma 73105
Oklahoma Health Care Authority Board Room

AGENDA

Discussion and Action On the following Items:

Items to be presented by Dr. Whitsett, Chairman:

1. **Call To Order**
   A. Roll Call – Dr. Graham

Items to be presented by Dr. Whitsett, Chairman:

2. **Public Comment Forum**
   A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Whitsett, Chairman:

3. **Action Item - Approval of DUR Board Meeting Minutes – See Appendix A.**
   A. December 14, 2004 DUR Minutes – Vote
   B. Memorandum of December 14, 2004
   C. Provider Letters to DUR Board

Items to be presented by Nico Gomez, Dr. Whitsett, Chairman:

4. **New Legislature Update and Budget Issues**

Items to be presented by Dr. Flannigan, Dr. Browning, Dr. Whitsett, Chairman:

5. **Update on DUR/MCAU Program - See Appendix B.**
   A. Therapy Management Quarterly Report
   B. Medication Coverage Activity Audit for December 2004
   C. Help Desk Activity Audit for December 2004

Items to be presented by Dr. Le, Dr. Whitsett, Chairman:

6. **Action Item – Update and Vote on Prior Authorization Status of Antidepressants - See Appendix C.**
   A. Current Prior Authorization Criteria
   B. COP Recommendations

Items to be presented by Dr. Chonlahan, Dr. Whitsett, Chairman:

7. **New Product Review- Cymbalta® – See Appendix D.**
   A. Drug Information
   B. COP Recommendations

Items to be presented by Dr. Moore, Dr. Whitsett, Chairman:

8. **30 Day Notice of Intent to Prior Authorize Bladder Control Drugs - See Appendix E.**
   A. Demographic Information
   B. COP Recommendations
   C. Economic Impact

Items to be presented by Dr. Browning, Dr. Whitsett, Chairman:

9. **Annual Review of Anxiolytic / Hypnotic PBPA Category – See Appendix F.**
   A. Utilization Review
   B. COP Recommendations

Items to be presented by Dr. Browning, Dr. Whitsett, Chairman:

10. **30 Day Notice of Intent to Prior Authorize Lunesta® – See Appendix G.**
    A. Drug Information
    B. COP Recommendation

Items to be presented by Dr. Patel, Dr. Whitsett, Chairman:

11. **Review and Discuss Multiple Sclerosis Medications – See Appendix H.**
    A. Disease Overview
    B. Oklahoma Medicaid Utilization Review
    C. COP Recommendations

Items to be presented by Dr. McIlvain, Dr. Whitsett, Chairman:

12. **Annual Review of ADHD / Narcolepsy PBPA Category – See Appendix I.**
    A. Utilization Review
    B. COP Recommendations

13. **FDA and DEA Updates – See Appendix J.**

14. **Future Business**
    A. PBPA Annual Reviews
    B. Neurontin™ Follow-Up Review
    C. Zofran® Follow-Up Review
    D. SMAC Update
    E. New Product Reviews
    F. Supplemental Rebate Update

15. **Adjournment**

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of DECEMBER 14, 2004

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.	X	
Dorothy Gourley, D.Ph.	X	
Cathy Hollen, D.Ph.	X	
Dan McNeill, Ph.D., PA-C	X	
Cliff Meece, D.Ph.	X	
Dick Robinson, D.Ph., Vice-Chair	X	
James M. Swaim, D.Ph.	X	
Thomas Whitsett, M.D., Chair	X	
(VACANT)		
(VACANT)		

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph./Clinical Pharmacist		X
Metha Chonlahan, D.Ph./Clinical Pharmacist	X	
Karen Egesdal, D.Ph./Clinical Pharmacist/OHCA Liaison	X	
Kelly Flannigan, Pharm.D../Clinical Pharmacist	X	
Shellie Gorman, Pharm.D./Clinical Pharmacist	X	
Ronald Graham, D.Ph., DUR Manager/Operations Director	X	
Chris Kim Le, Pharm.D.; Clinical Pharmacist	X	
Ann McIlvain, Pharm.D.; Clinical Pharmacist	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Neeraj Patel, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean	X	

Visiting Pharmacy Student: *none*

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Alex Easton, M.B.A.; Pharmacy Operations Manager	X	
Mike Fogarty, J.D., MSW; Chief Executive Officer	X	
Lynn Mitchell, M.D., M.P.H, Medical Director		X
Nancy Nesser, D.Ph., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D., Legal		X
Lynn Rambo-Jones, J.D., Legal	X	
Rodney Ramsey; Pharmacy Claims Specialist	X	

OTHERS PRESENT:

Warren Pieratt, Pfizer	Randy McGinley, Berlex	Michelle Martinez, Santarus
Michael Hathaway, BMS	Jeannie Gillmore, McNeil	Richard Ponder, J&J
Christi Davis O'Brien, Astra Zeneca	Mark DeClerk, Lilly	Andi Moore, Takeda
Rachelle McCoy, McNeil	Matt Johnson, Takeda	Tracy Copeland, Forest
Toby Thompson, Pfizer	Brian Maves, Pfizer	JoAnne Hargraves, Schering
Jalu Abbott, PharmCare	Jonathan Klock, GSK	

PRESENT FOR PUBLIC COMMENT:

Don Hamilton, Item #5	Pam Chadwell, Item #8
Marcialee Ledbetter, Item #5	Larry Sherwood, Item #8
Kent Abbott, Item #8	

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: Roll Call

Dr. Whitsett called the meeting to order. Dr. Brent Bell was introduced as the new Board Member. Roll call by Dr. Graham established the presence of a quorum.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

2A: Acknowledgement of Speakers and Agenda Item

Dr. Whitsett acknowledged speakers for Public Comment.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MINUTES**

3A: November 9, 2004 DUR Minutes

Dr. McNeill asked for a correction on page 7 of the DUR packet. At agenda Item 9, Dr. McNeill asked if the Bladder Control category **should** be tiered? Dr. Meece moved to approve minutes as submitted with Dr. McNeill's correction; motion seconded by Dr. Swaim.

ACTION: MOTION CARRIED

3B: DUR Board Meeting Dates for 2005

No action required.

AGENDA ITEM NO. 4: **UPDATE ON DUR/MCAU PROGRAM**

4A: Retrospective DUR Report: September 2004

Pediatric Populations: established, major drug interactions, age 0-21 years; narcotics, abuse potential only, age 0-21 years; and drug-disease level, contraindicated, age 0-21 years, with renal disease, asthma, epilepsy, migraine, or muscular dystrophy were selected for retrospective review for September 2004. Pharmacy and physician response was 60% and 32% respectively. Materials included in agenda packet; presented by Dr. Flannigan.

4B: Medication Coverage Activity Report: November 2004

The November 2004 activity audit noted total number of petitions submitted was 15,554 including super-PA's and special circumstance PA's. Approval/denial/duplicate percentages were indicated on the reports included in the agenda packet for this meeting; presented by Dr. Flannigan.

4C: Help Desk Activity Report: November 2004

Total calls for November 2004 numbered 18,477 (87.02% pharmacies, 8.42% clients, 2.11% physicians, 2.46% other); presented by Dr. Flannigan.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: **DISCUSSION & VOTE ON ADHD PRIOR AUTHORIZATION CHANGES**

For Public Comment, Don Hamilton: *I had a little handout here . . . pass out. I'm a general pediatrician from Tulsa. I work at the OU branch in Tulsa and work with the residency program. We have quite a number of patients with ADHD. Our best estimate is over 500. That changes daily due to a lot of different factors. And, first of all, I'd like to say we have been trained for the last few years to put together a unique kind of team approach to the care of these patients, so Dr. Marcialee Ledbetter is here with me tonight. She is a child psychiatrist and she, of the last few years we have worked together in the pediatric clinic, our feeling is that if more of these kids can get care in the general pediatric clinic without having to be referred out, that they will get, we can have more consistent care of the follow-up for them. And as you know, there's a lack of places, many times, to send these kids. So, she acts as our consultant. As our consultant . . . we try the best we can to manage as many of these kids as we can. So we have quite a number. Just a few things I'd like to point out is that ADHD is a chronic disease, like asthma, like diabetes. It's something that most kids are going to deal with throughout their lifetime. And we have to start approaching it that way as far as how we take care of them and medicate them and other treatments that we use. It's also associated with increased medical costs and visits, both in out-patient, in-patient and through the emergency*

department. And all this is backup up by my research, by studies. There is an evidence basis and expert agreement that treatment using medication, behavior therapy and a combination of both is effective for the management of this disorder. And, fourth, and one of the important things I'm here to talk about is that long acting medications can improve care in so many ways. It improves compliance. I have families that Mom has to drop the child at 7:00 in the morning at daycare. They go to school at 8:00 or 8:30, they go back to daycare, you know, being on short acting medicines means this Mom and family carting the medication around with them, multiple sources. It just doesn't work. And plus you have then the possibility, the increased possibility of diversion of medicine, and getting it in other hands. Allowing more consistent control of ADHD, like asthma, like diabetes, lessened side effects, gives kids more control of things throughout the day. It's pretty bad if you have ADHD to suddenly, your medicine starts wearing off in reading or math class before you get your next dose at lunch. So long acting medicines offer a very important way that we can kind of manage and control this a little bit better. Again, the PA process kind of, greatly affects us with as many patients as we have, being able to really do this. Also a very important part of management is finding the effective dose for the child, and that sometimes involves titration, starting out with a lower dose and moving up. Right now, the current process if the child is on a long acting medicine, and we want to change dose, we have to get a new PA. That takes time. With the controlled substance, by the time that gets through the process, sometimes we have to start all over and get a new prescription. And for the kind of patients that I serve, that's a problem. Transportation is an issue, many different things is an issue. So that affects us greatly. I'd just like to propose to you that the current process doesn't save us any money. It's, I have two people in my office that spend over 50% of their time just dealing with paperwork doing this. I could put them doing more effective things. I've got a nurse who has six, seven years of experience as a school nurse and then worked for a child psychiatrist for two years. I want her spending more time educating my patients and less time doing paperwork and things, that now she's spending so much of her time going through the PA kind of process. It also costs pharmacies and it also costs the Oklahoma Health Care Authority in dealing with this paperwork. And it also, short acting medicines dealing with, that is a problem for the schools. Many schools have had to cut back, do not have nurses and people on site to deal with medication and things like that. So I would urge, whether it be changed now or even a trial basis, that we look at that to cut back on prior authorizations for longer acting stimulants, because I think that this is and important tool to management of ADHD. I'd also like to say since I know that there are many people here from the pharmaceutical companies, that having these drugs affordable priced is so important for families, and I have even, a lot of my kids that have other insurance who cannot afford some of the long acting medicines. So we need your help however it is cutting back on your expenses and things so that these medications can be more available to kids with ADHD.

Dr. Whitsett: *There are questions? I guess one of the questions I have, maybe is what your recommendation would be to the Board? That we just do away with it completely and let . . . open it up for free prescribing to anyone? Any dose, any multiple time to change and to do away with any attempts to try to control costs and regulate usage?*

Dr. Hamilton: *Well, again I think we ought to look at the cost factor. I didn't really have time to review that, but I was presented with a paper, you know, shortly before I came here, looking at the cost issue, and if you take a short acting medicine three times a day, as many of these kids do, I question whether we're really having that much of a cost difference, you know, as if they were on a long acting stimulant. So, you know, it may be on a pill for pill cost less, but if they take methylphenidate three times a day, or dextro-amphetamine three times a day, sometimes that really adds up on the cost, too. And I don't know if we have that to track, but we need more availability to get the long acting stimulants and less paperwork.*

Dr. Whitsett: *Other questions?*

Dr. Graham: *Doctor, do you use the short acting stimulants at all?*

Dr. Hamilton: *Yes, I do.*

Dr. Graham: *. . . in combination with the long acting?*

Dr. Hamilton: *Sometimes, you know, because even the long acting medicines sometimes are gone by the middle of the afternoon, or early afternoon. Some of the kids need the short acting medicine in the afternoon to get through the evening hours. These are all just tools and I use every one of them because, again, they work differently, they work differently in some kids as far as the absorption rate, the length of time, and we have several child psychiatrists here that attest to that also. There are tools we have right now in controlling this disorder and others.*

Dr. Whitsett: *Do you think there's any issue at all regarding abuse of this category of medicines? Is that something we should forget about?*

Dr. Hamilton: *Well I think the abuse is much higher with the short acting medicines. Two of my patients over the last year, as they hit their middle school year, they were on short acting stimulants, were under a lot of pressure at school to divert their short acting stimulants. Longer acting stimulants do not have the street value, do not have as much abuse potential as the short acting ones. It can be crushed, snorted, injected. So, and plus when you're getting 90 methylphenidate tablets, it's easier to divert a few of those as I hear is not uncommonly done, than it is if you're getting 30 of a longer acting stimulant. Easier for parents to control that, too.*

Dr. Graham: *I think that one of the things that we experienced as a Board is that the Board members have had a hard time dealing with, when the once-a-days came out, they were to replace the short acting medications, but we haven't seen that trend. We've seen the long actings in addition to all the short actings that were, that were being taking. That's why I was asking that question . . .*
Dr. Hamilton: *You mean in combination?*
Dr. Graham: *Combination of those products. Do you see a, in your practice, did you see a lessening of the use of the shorter acting ones, with an increased use of your long acting ones, I guess is what I . . .*
Dr. Hamilton: *Well I think overall, that just, this is a chronic disorder and it's a 24-7 disorder too for a lot of kids that have severe symptoms, and so it's not just a school problem, so many times they do need medication at home if they're on a long acting stimulant that lasts till 3:00 or 4:00, they've still got five to six hours of the day to try to function, do homework and different things.*
Dr. Graham: *Do you ever use multiple doses of long acting ones?*
Dr. Hamilton: *Rarely. I have. I've had several kids who even, one of the longer acting medicines will last to 1:00 or 2:00, or 3:00 and they've still got six or seven more hours, they're rapid metabolizers of these drugs, and you know, unfortunately, there's not one formula that fits all and there's not one medicine that fits all. Many of you have been in practice as long or longer than I have, but this is kind of like back in the eighties when we treated asthma with theophylline and some kids could take and some people took TheoDUR Sprinkle and some took Quibron, and you know, got good drug levels on one and not the other. That's how but kind of for different mechanisms, how it seems, that some, you know, kids do very well on Concerta and some do better on Adderall XR. It's kind part of the art of dealing with this problem.*
Dr. Whitsett: *Questions?*
Dr. Hollen: *I have a question. Thank you very much. That was a very useful. I have a question as far as, instead of requiring the provider to do a new PA every time the strength changes, is there not a way for us to just place a cap on a maximum dose and anything under that dose?*
Dr. Nesser: *Well, what this proposal is to, to so they won't have to fill out a new PA.*
Dr. Hollen: *Okay, that's what I was reading . . .*
Dr. Nesser: *Yeah, yeah. We talked about that last month.*
Dr. Hamilton: *It's . . . I'd say one more thing. It's pretty common and I as a practitioner normally start kids on the lowest possible dose and then titrate up until we feel like things are better under control. Yeah, it's hard to do that this way, because every time you have to do a new PA, well yes . . . that would be a help.*
Dr. Whitsett: *The current proposal does away with having to acquire a new PA for changing dose?*
Dr. Nesser: *Right. There would be one initial PA in some cases, right.*
For Public Comment, Marcialee Ledbetter: *I should perhaps, my . . .what I'm going to say was the fact that I, it was not . . . planning on speaking specifically to ADHD medications but to child psychiatric issues, so I don't know if you want me to go ahead and speak or not.*
Dr. Whitsett: *Well, yeah, I'm not sure what . . . you've come a long way to . . . I would hate to . . . I guess . . . we have this proposal that we have put forth relative to adjusting the prior authorization process to this category of medications, so that's the category and there may be specific questions the Board members have relative to that and we are going to, I think, a little later, talk about issues that you might certainly be helpful relative to the . . . have your presence.*
Dr. Ledbetter: *Either way? Okay, so I can . . .I can . . . I'll go ahead and . . . okay. I also put together some recommendations. Again, they're not specific to ADHD. I'm board certified in general psychiatry in child and adolescent psychiatry. I moved back here to Oklahoma seven years ago. I was previously at University of Chicago where I was the Director of the Child and Adolescent Psychopharmacology Clinic there, and so . . . I am going to have a hard time distilling my seven years here in five minutes or so, but I'm going to try. In preparing to come down here today, I spoke with several of my child psychiatrist colleagues in Tulsa. They're currently providing in-patient services for Medicaid children. None of them are providing out-patient services, but they did previously. The majority of them . . . there's a series of reasons why they're no longer providing out-patient care, but one of the key reasons is the challenge that comes with the prior authorization process. I'm at OU/Tulsa. I do a small amount of out-patient, also practice in a residential facility and see the most impaired children at the Laura Dester Shelter, the Tulsa County DHS shelter. I cut back my out-patient child psychiatry practice down to a third several years ago, specifically because of the time that it took for the prior authorization process. I'd like to know . . . like to note that when I'm talking about these concerns, I'm really very genuinely interested in finding workable solutions and not just complaining. I do recognize there are significant cost issues, certainly with the psychotropic medications, but I'm very convinced that quality psychiatric care really brings with it money savings. While some of these savings may not be till these children reach adulthood, I believe there are immediate savings. I don't think this is just an academic point and I personally have experienced this in the last couple of months. I had two children who were denied particular medications. They had been stable on their medications. One was hospitalized for about two-and-*

a-half to three weeks. The other one, I was able to keep out of the hospital, but I really, these kind of things need to not be happening. My colleagues that I spoke with in Tulsa who work on in-patient units also note that they frequently are seeing admissions with a statement that this child was on certain medications, they are no longer able to access them, and so they're no longer stable, and they're now being hospitalized. I do think the issues that are related to this are complex and well beyond the scope of the DUR Board, but they directly affect the care of these children and impact the entire system. We certainly don't have an adequate number of child psychiatrists and at this point, there's absolutely no motivating factor for child psychiatrists in the State of Oklahoma to provide care for these children beyond altruism. Reimbursement is not adequate for the time that you need to spend for some of these sickest kids, and the difficulty in accessing quality psychotherapeutic services is another barrier. And so that means there's often much additional time you have to spend that's not going to be reimbursed to keep these children stable, with phone calls and various emergencies. An additional problem I recognize that you all have to deal with is the fact that there is inadequate research in child and adolescent psychopharmacology with very few FDA indications outside of, for the most part, the ADHD medications. So it makes it difficult for you all to develop appropriate algorithms. That being said, there are a couple of concerns I would like to touch on. One of the things I've run into over several years is unexpected changes in the PA process that take me by surprise and I think that I understand what the algorithm is and then something gets denied and I learn that the algorithm has changed. It would be very helpful for practitioners to somehow have regular updates on what the protocols are so you don't run into these kind of problems. A recent example that we ran into the very same week that we initially were for the first time required to do prior authorizations for SSRIs, Dr. Hamilton showed me a DUR Newsletter that stated that no prior authorizations would be required for particular SSRIs that we just had to do the prior authorizations on, so that's confusing and frustrating and time consuming. I will say frankly, that there have been times that particular recommendations and comments have indicated to me that people really are not well informed about child psychopharmacology and I find it frustrating to try to talk with people who don't have the education that I have in regards to psychopharmacology and explaining a particular medication regimen. I would also say that I think sometimes some of the actions are adversarial and not helpful. Recently I was shown a little disclaimer that the physician is now required to sign regarding use of Paxil in children. Now, you know, we've all heard about the SSRI controversy but frankly, I don't see how that's helpful for physicians to sign what I considered really an inflammatory statement when their goal should be to effectively treat children. Another example that I think has not been particularly helpful, I have a child that for many years has responded well to Adderall 20 mg, three times a day, so it is a higher dose of Adderall and I'm required to acknowledge on a form that I have not, through my treatment, caused this child to be psychotic. And I have to say, if I am expected as a physician, to. . . to be able to know that, yes that's right, this child is not psychotic because of my treatment, then I really need to not be practicing medicine. And I hope that we can find ways to work together to aim for quality and not set up particular paperwork forms or particular statements that are going to be adversarial for those of us trying to take care of these children. I also find as a physician who does spend most of my out-patient time with only the most impaired children, what that translates into for me is that I have multiple, multiple prior authorizations and it's part of why I hardly do any outpatient psychopharmacology treatment now, because I can't afford that kind of waste of my time, and I really think it would be helpful to allow those of us who are willing to commit ourselves to the work of taking care of these children to not have to go through some of the excessive PA process. I had passed around a recommendation and I don't . . . I've spoken long enough, so I don't know if you wanted me to talk about any of those or just open it for questions.

Dr. Meece: *Doctor, what do you find takes so much filling out a PA? I don't, I mean, basically the PA is filled out at the pharmacy and sent to you for a diagnosis and a comment and a signature.*

Dr. Ledbetter: *Right. There are a series of problems. One is the expectation that you have to go back through and note what the failed trials have been. And that does take some time. And sometimes you have to, and I think the expectation is you know what the failure was with the trial. The other thing that commonly, well, at times it commonly has happened, is that I'll fill out a PA and then it gets rejected, and then I have to do, have to call somebody on the phone and talk with them on the phone and explain why I think this is an appropriate medication for a child. So sometimes it's not as simple as just, you know, signing my name and having it faxed. There's a lot of other layers that I run into.*

Dr. Meece: *Basically, the computer finds the Tier 1 failures, right?*

Dr. Nesser: *Well in the stimulants, that's what we're going . . . we're looking at approving.*

Dr. Bell: *But it won't find a failure that's been on somebody else's insurance.*

Dr. Nesser: *Right. Right.*

Dr. Bell: *I find that sometimes I will choose a different treatment rather than go through it. For example, I've done well with kids on Strattera and a small dose stimulant. I know that's . . . with your prior auth, I agree. You need to be able to use a small group of stimulants. Let me ask you a question about . . . I'm using, just like you are I think. I'm turning toward more and more long acting stimulants. I think in a few years we're going to, everybody's going*

to try to do that. I'm having so many parents that the schools do not want to give those noon doses, do not want those stimulants on their campuses, and I try my best to use long acting stimulants rather than have a kid have to take a bottle to school.
Dr. Ledbetter: *That's true, although I'll also comment . . . I just had a patient who we've been through, through the whole ADHD algorithm of the stimulants. The one medication he responds well to is brand name Ritalin and that was denied, and I came up with a little coupon to try Focalin out for this child and his grandmother, when I came to bring out the coupon, because he's been stable for I'm not sure . . . two years I think, on brand name Ritalin and before I . . . he got stable. He, among other things, burned down the family's barn and she was weeping because the brand name Ritalin has been denied.*
Dr. Nesser: *I'm curious about what PA's you're talking about, because until the SSRIs were PA'ed last month, the only mental health drugs that were PA'ed were stimulants and so I'm just curious . . . that so many categories . . .*
Dr. Ledbetter: *You know, I've had a variety of things over the years. An example would be I had a child, well he's not a child anymore, he's grown up. But . . . who had a strong family history of bipolar disorder. The mother had had an excellent response to Neurontin and had failed the standard algorithm that you do for bipolar. She's failed lithium, depakote, Tegretol . . . had done well on Neurontin. He came in with a pretty unusual classic history of bipolar for a teenager and so I went ahead and started him on Neurontin. He had an excellent response and then that was denied.*
Dr. Nesser: *That's never been denied under Oklahoma Medicaid.*
Dr. Graham: *It's not Medicaid.*
Dr. Nesser: *That was some other insurance.*
Dr. Ledbetter: *It was Heartland. So some of my struggle over the seven years certainly was with Heartland PA process. And many of the challenges were those . . .*
Dr. Nesser: *Right. I just want to clarify that that is not what this Board does. That was not their . . . their purview to . . . that was Heartland's program, not . . . it was not Medicaid fee-for-service and that's what we're doing here, so I want . . . I would just want to be clear that we're talking about the same thing. I'd also like to see this whatever the statement is that, about the . . . not causing psychosis. I'd like to see if that's from us or, or from another company.*
Dr. Ledbetter: *There's . . . there's some form . . . no, this is Medicaid. There's a statement faxed and you have to say that whether or not the child's had any psychotic symptoms . . . I can pull it from a chart.*
Dr. Le: *It's not a form. The only thing we have is a regular petition form that if you exceed the maximum FDA recommended dose, we send a series of questions where you answer them. It's not a form . . . you answer them. You either type it out or you can handwrite it and fax it in to us and it just tells us how long the client's been on it at that dose, if you're experiencing any adverse effects from it. It's not a form. We don't have such a form.*
Dr. Hollen: *And it's a question that they're required to answer.*
Dr. Le: *Yeah.*
Dr. Whitsett: *When someone has exceeded the upper limit of the FDA recommended dosage which is something that we felt was a reasonable thing when there are a lot of people . . . certain drugs that are abused and people are prescribing them well above the upper limit of recommended dosage . . . that give a red flag . . . need to control that with PA.*
Dr. Nesser: *Right. Not all doctors are as educated as you and so we just want to make sure that everyone has considered those facts. So, I mean, I'm sure that if everyone who could write those stimulants had your education and experience, that would not be a concern for this Board, but that's just not how it really is.*
Dr. Whitsett: *There are some pretty large doses getting prescribed . . . usual circumstance.*
Dr. Ledbetter: *Yeah, that's what I understand, and I share your concern. I think the specific thing that I find most frustrating is that I take care of the sickest kids, and I'm willing to do it and I'm lucky to be at OU/Tulsa where I can do it on a salary and not have to worry, but I . . . there has to be some recognition of how challenging it is and how time consuming it can be to do it the right way and keep these kids healthy and keep them out of the hospital.*
Dr. Whitsett: *Well, we will take a look at that and see what, see if there's error in our ways.*
Dr. Hollen: *Is there anything on the form that identifies the speciality of the providers, that you know . . . do you know whether you're dealing with somebody who's board certified in child psychiatry or just that someone . . . .*
Dr. Nesser: *I don't think we want to get into verifying and all that.*
Dr. Hollen: *Why don't you verify? I mean, I would think that might be something . . .*
Dr. Nesser: *Well, one of the physicians we've had the most problem with is not a board certified psychiatrist, but he identifies himself as a psychiatrist. So if we took his word that psychiatry is his speciality, we would then grant exception to him. So, so that's the problem, is credentialing. Unfortunately.*
Dr. Hollen: *Did we ever get that figured out and taken care of? I assume that's the one that was using the dosing that were, I mean that wasn't even excessive . . . that was crazy.*
Dr. Nesser: *Yeah, yeah.*

Dr. Whitsett: *I guess we need to, at this point, look at our recommendations . . . change here, too. And if you want to, do you just want to go over that again real quickly so it's fresh in everyone's mind?*
Dr. McIlvain reviewed the recommendations and other materials included in the agenda packet.
Dr. McNeill asked how long of a trial of Tier 1 medications is required prior to moving to a Tier 2 medication. Dr. McNeill asked if the use of past medications has to be continuous in order to move to a Tier 2 medication. Dr. McNeill asked if a client moves into the state from another state and was on a Tier 2 medication, does this require a Tier 1 trial. Dr. Bell recommended that the computer look as far back as a year in history for trials of medications. Dr. Whitsett suggested not to place a specific length of time for a trial but to use judgment. The Board agreed to have the computer look back in history for a year for previous trials.
Dr. Meece moved to approve; motion seconded by Dr. Gourley.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: DISCUSSION & VOTE ON PRIOR AUTHORIZATION OF ZEGERID®
Materials included in agenda packet; presented by Dr. McIlvain
Dr. McNeill moved to approve; motion seconded by Dr. Swaim.
ACTION: MOTION CARRIED.

AGENDA ITEM No. 7: DISCUSSION & VOTE ON PRIOR AUTHORIZATION OF XOPENEX®
Materials included in agenda packet; presented by Dr. Flannigan.
Dr. McNeill asked what explanation would be acceptable not to use long acting bronchodilators.
Dr. Meece moved to approve; motion seconded by Dr. Robinson.
ACTION: MOTION CARRIED.

AGENDA ITEM NO. 8: REVIEW & DISCUSS ECONOMIC IMPACT OF PRIOR AUTHORIZATION ON BLADDER CONTROL MEDICATIONS

For Public Comment, Pam Chadwell: *My name is Pam Chadwell. I'm a P.A. practicing in longterm care in the Oklahoma City area. Our group sees approximately 800 patients and so I'm here for the elderly female that I treat. So many of our patients are stable right now on their incontinent medication and it concerns me that we're going to change them to a generic that we know is more anticholinergic and it causes more falls. Also instead of having to give them one day a dose which I give many of my patients now, I'll have to give them two or three doses during the day, and here we go again with compliance issues. A lot of these patients don't want to take medications because they take so many during the day, and then if the patient is not getting their medications, the ones that, the only function they have at the nursing home. This is not longterm care, really it's end of life care. They live in a half of a room and the only joy they have in the day is going out to eat and going to a few activities. So if they are not compliant with their medicine because they have to get it three times a day, you find these people isolating themselves to their room. They're not drinking water now because they're worried about wetting on themselves. They become dehydrated. We have more urinary tract infections and the people who are trying to get to the bathroom are slipping in their urine and falling. So it's a great concern to me. I know we only have X amount of money for X amount of patients, but in longterm care, there's such a waste of money it's ridiculous. I mean, it's so sad for me when at the end of the month we pay a pharmacist to destroy all the medications with Medicaid. One home I was at, we actually threw away $60,000 in one month of pills. I mean we're throwing away millions of dollars. We can help children, we can help the elderly. I mean we need to do something for these productive people who now spent all their money and they're on Medicaid. They deserve care. So, that is my concern. Just making sure that some of the patients, there's not that many elderly patients that are on some of the long acting and some of the incontinent medications that don't have so many side effects, so I really don't even see changing that's going to make a big difference. But the few that are and they do more activities, I mean I think they should have joy at the end of their life. And some of this makes a major difference in them. It's the same way when we went through the antidepressants. You know it's very difficult for me. I've had patients stable on medications and now I am taking them off and going back to the recommended drugs. And we've got a couple of people, it's just not working. And it's sad, because that's going to be all of us. We're living a very long time. Unless you're filthy rich, you're going to end up in a nursing home.*
Dr. Swaim: *Why is compliance an issue in a long term care facility?*

Ms. Chadwell: *Well you have first of all in the long term care, you're, you have someone with three days of education passing out pills. We are recommended, you know we work with pharmacists hand in hand around every one of our buildings. So for all of our patients, you know they're all on calcium three times a day, they're on multi vitamin, they're on vitamin C. We're supposed to have like nine medications and it's very difficult. These people are at the nursing home for one reason. They're so ill they can't care for themselves. So we have a lot of pills. Have you ever taken pills in a little you know, they crush them, they put them all up, they put them in jelly. They just get to the point they are sick of taking pills. So anytime that I can give them a medication that's long acting, it's so much better because you improve their quality of life. And they deserve quality of life. I mean not all of them have lost their mind. Some of them are there and you know their joy is going out to the dinner table with a few people and be able to discuss what's going on or talk about their family. But I promise you when they start getting, wetting on themselves they isolate their self into their room. They get more depressed, you have to think about an antidepressant, you know. We're pushing more liquids to . . . times they get so dehydrated we have to send them to the hospital or they get a urinary tract infection. We have had people slip because of urine, trying to get to the bathroom. So we have multiple problems. It's just a crime that we throw so much money away here in Oklahoma in Medicaid drugs.*

Dr. Swaim: *You know there's a recycle program?*

Ms. Chadwell: *We need to take those . . .*

Dr. Gourley: *No, I don't think she does.*

Dr. Swaim: *I don't think so.*

Ms. Chadwell: *They are trying to get it approved so they can go to some of the clinics. The first batch was several homes, because a couple of homes that I go to were selected. They could go if it was a full pack. Now if I had 60 pills on one pack and two were gone, that got discarded. And this might be an antipsychotic medication that someone else can use that are, you know, on one's staff at Deaconess at the psychiatric hospital and some of those people are on Medicaid and can't get any pills. They don't have any money and they're noncompliant. We throw away so many pills that it's phenomenal. Buckets. You will go in and there will be five gallon buckets full of medication, and that's your tax dollars going down the toilet. We're paying a pharmacist to destroy them.*

Dr. Whitsett: *Well, why, why are you . . . are there extra pills there?*

Ms. Chadwell: *Anyone who, if like we order pills, because you don't have a pharmacist at every nursing home, so what you do, you're working with a pharmacy group so you order medications for the month. And so, Mrs. Smith has $1800 dollars worth of medications for the month. Mrs. Smith died on . . . . ordered this January 1st and she died on January 2nd. One pill out of that pack, it is thrown, every one of those are punched out by a pharmacist and destroyed . . . $1800. If you have a reaction . . .*

Dr. Whitsett: *. . . the recycle mechanism?*

Dr. Swaim: *Yes, there is and I don't . . .*

Dr. Whitsett: *Well I don't think these people should . . . are out of compliance then.*

Dr. Hollen: *They do know about it.*

Ms. Chadwell: *We are destroying . . . the recycling program, I work with some of the pharmacists, because the people in the nursing home, we're distraught about this. I mean we see kids that need medications that are on Medicaid and I want my elderly to get pills, too, the ones that they need and we're actually . . . we calculated. It's about $13 million is what we are estimating.*

Dr. Whitsett: *Well I can understand. I appreciate that. You're making your point very clearly, but the issue is why are they doing that? Why don't they use the existing recycling program. As they're not using it what needs to be done to educate them at the . . . the mechanism?*

Ms. Chadwell: *We don't have a recycling program that goes to . . . back to the State. These pills need to go back to the State. All they have to do is take the label off and recycle them to the State. What they're going to try to do is what the trial program was . . .*

Dr. Swaim: *Well I am too, and I don't have all the details.*

Ms. Chadwell: *There was going to be a few picked. If you're in the total card, because I work with some of the pharmacists who are trying to . . . it's going to go to free clinics. But again, this is (unintelligible). These are people that need medications. This is your tax dollars at work.*

Dr. Whitsett: *We understand that. You've made that point three times now.*

Ms. Chadwell: *Well it's frustrating. As a taxpayer.*

Dr. Whitsett: *But we need to know what . . . you've made your point and we'll take it into consideration to see if there's a way of not discarding millions of dollars of medicine.*

Dr. Hollen: *I think the consulting pharmacists are overwhelmed. You're looking at a very few number of pharmacists that are able, and they're covering a number of homes. They're stretched to even do, and this is my perception of it, is they're very stretched to even do what they're responsible as far as reviewing medications,*

working with providers to try to have them take on, this is like a whole other job. Because I mean, I've seen closets that are literally full, and there's no time to go through there.
Ms. Chadwell: *And then any medication that . . . if any medication has a lot of side effects to it . . .*
Dr. Whitsett: *If you offer an incentive for someone to do that . . . . they'll find time to do it.*
Dr. Hollen: *The only incentive is to go ahead and fill that . . . I mean . . .*
Dr. Whitsett: *Any other questions?*
Dr. Hollen: *Do you think the age of 65 is the average age that you see incontinence being a major issue for most of your patients?*
Ms. Chadwell: *You know our average age is an 87-year old female. So you know there's very people that need those one time a day dosing but what I'm concerned is the fall and the anticholinergic side effects because there's so much litigation out in the nursing home. Who's going to care for these people? Because if someone falls, you'll have to account to that with an attorney. Thank you.*
For Public Comment, Larry Sherwood: (tape ended, no comment on reverse "B" side)
Dr. McNeill: *Mr. Sherwood, in your experience, I don't care, I don't want to deal with the pharmaceutical companies literature, I want to deal with your experience for just a minute. Breakthrough incontinence in short acting versus a single long acting anticholinergic type pill. Do you see it more in one than the other?*
Mr. Sherwood: *Well you see it more in the short acting because people don't take them.*
Dr. McNeill: *And I understand compliance in nursing home, long term care facility . . . I can appreciate that. But assuming for just a second they did take them. Is there a difference in your experience?*
Mr. Sherwood: *Yes. They have the dry mouth and they start refusing to take them. The short term. Dry mouth becomes a big issue with people who take these medicines. It's, if you want to try it and find out what it's like, stuff your mouth with cotton every two hours for the next 24 hours and drink one liter of fluids in a day's time. That will give you the same idea that they go through with a dry mouth.*
For Public Comment, Kent Abbott, American Society of Consultant Pharmacists: *I've got some handouts that will kind of tie together. Going after all the passion that we've already exhibited, I can, I can tone myself down just a little bit. My name is Kent Abbott. I am representing the Oklahoma Chapter of American Society of Consultant Pharmacists. And certainly, your duties, you guys' duties are pretty tough trying to contain the cost of medications and we applaud you for it. As a matter of fact, even though it doesn't feel like it, most of us in long term care pharmacy are in that process partially for what they just discussed. We don't want to destroy it. And I might just take a minute here just and explain the recycle because there was clearly some question regarding that. Currently at the Governor's desk, there is a recycle Bill to be signed. It essentially, I believe that it will be signed and it has also been handed out to the State Board of Pharmacy for approval. It does modify the two punches out. It takes it down to if there's 50% less or 50% of it left, then it can be brought back in or I should rephrase that . . . it can be given to a not-for-profit free clinic environment. So it's not actually being recouped by the State of Oklahoma. It's just being diverted, maybe diversion's a bad word . . . I don't want to use that one. It's being reissued for use to these, these patients that do not have the ability to purchase it, but for whatever reason, kind of fall through a crack. To take care of them. It has been broadened. It's not just, it's not as limited in the therapeutic categories as it was, but it's still falls way short of recapturing that money that would help the State of Oklahoma. It is better than flushing it down the toilet. It is better than doing nothing with it. But I can also tell you that the consultant pharmacy groups, as early as 1992, were suggesting that we were wasting a lot of money. That we needed to do something different. We actually made a proposal that included, let's bring it back into the dispensing pharmacy. Whatever dispensing pharmacy it was, if it, if it's not over, if it still has at least six months of shelf life to it, then we will use it and we will reissue it to patients. All that was asked at that time which was, it really hurt, but we said you know, we're doing a service. we're going to recover millions of dollars. Pay us two or three dollars to recover this money. And it was long before this group, but it was laughed out of the system. It was not going to be allowed. So you know, for twelve years we've been saying we've been destroying twelve, fifteen, twenty million dollars a year, that we should try to recapture all of . . . but only just now are we kind of getting to that point where we're going to try to do something about it, but it is, but it is not still going to help the State budget system. So, you know, if you have questions about that, I'll try to answer them. I was actually on that committee that developed this new stuff, so . . . Yes sir?*
Dr. Graham: *I have a question, Kent and maybe you can explain to the, to the P.A.s that were here and also to the audience maybe, what a, why a pharmacist, or why anybody, why they can't just redistribute those pills without certain guidelines?*
Mr. Abbott: *Federal law.*
Dr. Graham: *But besides that even. If you were, if you were taking the responsibility of distributing them, can you give us some ideas why, through litigation or whatever, you might not want to touch those.*
Mr. Abbott: *Well, from a State level, there's been wording added, there's been wording that has been added to the current regulation that we're going to operate under that holds us legally not responsible if there's been some contamination to the drug. We can only look at it, determine that we believe in all best conscience that it's not been*

contaminated with and that it should be re-used. There is, there's certainly a legal problem with that. Secondarily, and we don't want to discard it, is the, is the Federal mandates that say that we cannot transfer this from one patient to another. So it makes it very difficult, and then we've got State laws that say that we're going to follow the Federal laws. So there's a lot of things that have to be wrapped up in that. Do I want to take back a pharmacy X's product? I do not because I have absolutely no assurance. Do I believe they did the right thing? I absolutely do, but I can't guarantee it. What I would prefer to do is take back my own product that was dispense, you know. Reverse charge it back out of the system, charge back for the correct amount of the, the corrected amount that the patient actually used, and then be able to re-use the product. I believe it's the best solution for the State, I believe it's the best solution for the pharmacy, I believe the pharmacy's entitled to be paid for that. But I don't want to take back. . . my generic pharmacy is always Joe's Corner Drug, so if there is a Joe's Corner Drug in here, I don't mean anything by that. I just don't want to take back Joe's. You know, I want to take back what I was responsible for doing.

Dr. Graham: *One last question. What, now I know I think you're associated with what company?*

Mr. Abbott: *PharmCare.*

Dr. Graham: *Okay. What type of policy do you guys have towards nursing homes when you, when you dispense medication to a nursing home. What is the timeline that you guys renew those, those prescriptions? Like for automatic refills?*

Mr. Abbott: *Okay. No such thing as an automatic refill. First, at least in our company, it's a demand process. In other words, unless the nursing staff reorders it, we don't send it. They have to authorize us to send it.*

Dr. Graham: *Do all companies do that?*

Ms. Chadwell: *Yes. I work for NeighborCare and OmniCare and it's the same thing. You have to, you have to have authorization.*

Dr. Whitsett: *On a monthly basis?*

Dr. Graham: *It hasn't been in the past, has it?*

Mr. Abbott: *The real answer is that the system is designed revolving around a 30-day supply, and I'm using that roughly, but 30, 31, up to a 34-day supply of medication. So if we send out and there's actually another opportunity I guess to suggest something . . . if we send out a 14-day supply because we, we want to make sure that they, it's, they're going to tolerate it or the nursing staff says, hey, they're really bad. Maybe we don't need all of it. We send out a 14-day supply. The patient lives past that and that gets repeated two or three times, then we get a nice little notice or we get a nice little call from them saying, why are you dispensing a 14-day supply? We're, we only want to pay one dispensing fee and which, by the way is $4.15. We only want to pay one dispensing fee and you're hitting us twice a month for this. Well, yeah, but we don't know that, you know, we don't know that the patient has really improved that much or has declined that much at every given dispensing point, so you know it's kind of a catch-22. We could limit ourselves by dispensing fourteen or fifteen days supplys. We could limit the waste that we have, but the risk to the State is that they might end up having to pay two dispensing fees. I would submit and this is, this is Kent's, Kent's, Kent's thoughts, so it's, has that much value probably, but that we would save far more by paying two dispensing fees than we, than we would save by flushing this stuff down the toilet or, for that matter, giving it to a, a non-profit free clinic setting. We would, actually, Pam's suggestion that it's around $13 million I think is low. I think we're looking at $20 to $25 million, in reality.*

Dr. Whitsett: *Are people ordering refills of medications on patients that are not taking it, but they say, well here's what Mrs. Jones, here's her list of medications. She may have stopped it a month ago, but it's still, you know, the list somewhere. Do they just automatically have a refill list and it keeps coming in or . . .*

Mr. Abbott: *No, no. It doesn't work that way. Actually what, at least in our system, and I believe I can speak for both NeighborCare and OmniCare, the system is designed, it's in a blister pack. And whenever they get down to like seven to eight doses, then they peel off a label saying that they need to reorder it and they put it on a sheet and they reorder it that way. So theoretically, theoretically they've used the stock down to the point where they have made a determination it needs to be reordered. It's not on just a sheet that they check off.*

Ms. Chadwell: *You know, that's one thing too. In long term care you cannot force any patient to take a pill. So you're giving them the medication. If they refuse it on that day, it's already punched out, it's discarded and it's counted for. If they refuse it for ten days you still, if their family says you're not giving that, then you're in trouble because you're not, you can't force them to take anything because they have the right to fall out of the chair, they have the right to not take any medicines, take a bath . . . I mean we have no control.*

Mr. Abbott: *So, so, what, what is, another point that Pam's making is that the way our med aides are instructed and required by survey process, by inspection processes, you must push the med out, have it ready to give the patient, but if the patient refuses that medication, then you have to go back in five minutes, according to policy, but go back in five minutes and try it again, go back in five more minutes and try it again, and then if they refuse three times, then we have to destroy it right on the spot. So meds get used up. I don't know, I don't know an answer. We have a duty to try to get them to take their medications, but and I don't know another mechanism beyond that. But meds that we as taxpayers pay for still get wasted even in a perfect world. They would get wasted.*

Ms. Chadwell: *And that's why we're so concerned about getting medications that we can give one time a day because we have less waste.*
Mr. Abbott: *We do. We actually do. Of course, I'm here. . . did I . . . I stood up here about bladder control didn't I? Let me just say, I've handed out some handouts that have substantial information and study about the differences between bladder control medications that are immediate release versus those that are long term . . . long term care. In . . I work in long term care. But those that are long term release, long acting medications, they're, and I've provided you with a study, a recent study of 117 patients that there's a 45.9% reduction in falls from using long acting medication versus the short acting immediate release. The reasoning for, the reason for that is the adverse effects. They have blurred vision, they have, they have blurred vision, they have dry mouth, they have stumbling problems. They're already compromised because they don't have that good a gait as it is, you know. We're just adding to that by dumping a total dose on them where we can control that if we can spread it over time. So, you know, I think it's incredibly important that you realize that we've got compliance issues that are easier to meet, we can lower their risk of falls and you know, of, of, there's, approximately 250,000 falls a year in the U.S.*
Dr. Whitsett: *I think we're going to break in here. . . too much time. That point's been made. Other questions?*
Mr. Abbott: *Could I just say one other thing? The survey process uses the BEERS list, the BEERS criteria and if you, if a medication is given that is on the BEERS criteria list not to be given meds, then immediately that home is hit with a deficiency. Immediately. If we get to the trial lawyers section of it, if that doctor writes an order for an immediate release and it's on the BEERS, or writes for any drug on that BEERS list and they decide to litigate it, which we're pretty sure they probably will, it's immediate guilty, because this is the criteria that is used both State and Federal on the drugs not to be used. We're recommending a drug right here that is on the BEERS list. The immediate release, anticholinergics, antispasmodics are on that list. So if we do that here, then we're opening up the whole can of worms, litigation wise. That's all I have.*
Dr. Gourley: *I'd like to comment to that. Actually I admit patients to the hospital that come from nursing homes all the time and they inevitably do have drugs that are prescribed for them that are on the BEERS list. So I really do not believe that it is an absolute prohibition of drugs that are on the BEERS list. The consultant pharmacists are required to review and to make recommendations and to point that out to the physicians, but I do have patients admitted from nursing homes that are on drugs that are on the BEERS list.*
Materials included in agenda packet; presented by Drs.Gorman and Moore.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **REVIEW & DISCUSS PRIOR AUTHORIZATION REQUIREMENTS IN CHILDREN UNDER 18 YEARS OF AGE WITH SSRIs**
Materials included in agenda packet; presented by Dr. Le.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **REVIEW & DISCUSS CYMBALTA®**
Materials included in agenda packet.
(DEFERRED TO JANUARY 2005 MEETING.)
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **REVIEW & DISCUSS MULTIPLE SCLEROSIS MEDICATIONS**
Materials included in agenda packet.
(DEFERRED TO JANUARY 2005 MEETING.)
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **FDA & DEA UPDATES**
Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 13: **FUTURE BUSINESS**

13A: PBPA Annual Reviews
13B: Neurontin™ Follow-Up Review
13C: Zofran® Follow-Up Review
13D: SMAC Update
13E: Supplemental Rebate Update
13F: New Product Reviews

Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 13: **ADJOURNMENT**

The meeting was declared adjourned.

The University of Oklahoma College of Pharmacy

Pharmacy Management Consultants
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Oklahoma City, OK 73190
(405)-271-9039

Memorandum

Date: January 3, 2005

To: Nancy Nesser, DPh, JD
Pharmacy Director
Oklahoma Health Care Authority

From: Ron Graham, DPh
Operations Coordinator / DUR Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of December 14, 2004.

Recommendation 1: Discuss and Vote on ADHD Prior Authorization Changes.

The DUR Board moved to change the prior authorization requirements on ADHD medications for children and carefully monitor it and bring the issue back to the DUR Board in six months for follow up review.
MOTION CARRIED.

Current Process:

Tier 1 drugs are set in the computer system to pay without PA for clients up to 21 years of age; PA is required for adult clients. Tier 2 drugs are set to require a PA for all ages. Providers must submit a new PA petition every time the drug dosing strength changes.

Changes:

- Tier 1 stimulants would be in the step therapy edit as Tier 1 and on the drug file as PA for over 21 years old.
- Tier 2 stimulants would be in the step therapy edit as Tier 2 and on the drug file as PA for over 21 years old.
- Strattera would continue to have a PA on the drug file for all ages. This would provide a means to monitor concurrent use of stimulants and Strattera.
- Quantity limits of one unit per day would be placed on the Tier 2 drugs. Any quantity greater than this would require a PA.

How this would affect clients:

- **Adults:** The process would stay the same as it currently is for adult clients - all drugs in this category would require a PA, including all dosing strength changes.
- **Children up to 21 years old:** Everything would stay the same except the following: when the pharmacy tries to run a claim for a tier-2 drug in this category, the computer would look back one year into the client's Medicaid claims history. If the computer finds any drug in this category in the claims history, the computer would allow the tier-2 ADHD/narcolepsy drug claim to pay without requiring a PA, as long as the claim does not exceed the quantity limit. If the claim does exceed the quantity limit, PA would be required.

Recommendation 2: Discuss and Vote on Prior Authorization of Zegerid® (Omeprazole Powder for Oral Suspension).

The DUR Board moved to approve the prior authorization requirements for all Zegerid ® products as follows.
MOTION CARRIED.

Current tiers:

Anti-Ulcer Medications	
Tier 1	**Tier 2**
Prilosec OTC & generic rx omeprazole	ranitidine (Zantac) – all forms except tablets
esomeprazole magnesium (Nexium)	brand rx omeprazole (Prilosec)
lansoprazole (Prevacid) capsules	rabeprazole sodium (Aciphex)
pantoprazole sodium (Protonix)	lansoprazole (Prevacid) – tablets & granules

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Recommendation:

Place all Zegerid products on tier-2 status. Criteria for approval would be the same as the criteria for approval of Aciphex: a documented 14 day trial of a tier 1 anti-ulcer medication within the last 60 days.

Recommendation 3: Discuss and Vote on Prior Authorization of Xopenex®.

The DUR Board moved to approve the prior authorization requirement for Xopenex®.
MOTION CARRIED.

Recommendation:

Xopenex® (levalbuterol) use in excess of 90 days of therapy in a floating 360 day period will require prior authorization. The current quantity limit of 288units/30 days supply would still apply.

- In the prior authorization request, the prescriber should explain why the client is unable to use long acting bronchodilators and/or inhaled corticosteroid (ICS) therapy for long-term control per NAEPP guidelines.
- Clinical exceptions will be made for clients with COPD.

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December 13, 2004

University of Oklahoma
College of Pharmacy
Pharmacy Management Consultants
Attn: Medicaid Pharmacy and Therapeutics Chairman
P.O. Box 26901; ORI W-4403
Oklahoma City, OK 73190

To Whom It May Concern:

I am sending this letter to express my increasing concerns regarding the Medicaid Pharmacy Program.

I am a psychiatrist and typically deal with difficult and frequently treatment resistant cases. Most of the individuals I deal with, whether they are adult or children have already been in treatment and failed therapies, which has led to their referral to me. I suspect this is the case with most psychiatrists, but it is certainly representative of my practice. However, in reviewing these individuals medical history, it is very clear that many of these individuals have gone through multiple medication trials from their primary care physician, whether it is an internist, a family practitioner, or a pediatrician prior to coming to my office. I am finding it increasingly difficult to provide proper therapy to my patients because what I view as micromanagement by the Medicaid system. In particular, I am referring to denials of medication treatment because they do not fall within dosage ranges that are listed in the Physicians Desk Reference or cases where a medicine is prescribed at different frequencies than is listed in the Physicians Desk Reference. I am sure that most pharmacists and certainly any physician that has been in practice realizes that patient care needs and prescriptions practices very often fall outside what is listed in the PDR.

In particular, I find this frustrating because there is not even really an Appeals Process now. I will simply get a notification from the pharmacy that this dose has been denied or that it is not covered. Ultimately, it is my patients who are suffering with this. I of course try to use standard therapies first, but there are simply many cases where this will not suffice and as I stated previously, I find it incredibly frustrating when I believe I have a treatment option that will benefit a patient that I believe is safe and efficacious and you simply refuse to consider it or cover it.

(Continued)

I understand that you are trying to run, maintain, and manage a large pharmacy program that has many recipients, but I think you need to ultimately remember that you are charged with caring for these individuals. I believe that when you maintain such rigid protocols that you are ultimately failing and what should be your primary concern.

I would appreciate some sort of response from you in regards to this. I feel strongly enough about this that I would be happy to meet with you or if nothing else to at least converse with you on the telephone because I sincerely feel at times that you are tying one hand behind my back preventing me from doing my job.

I appreciate your attention to this matter. Please contact me, and I look forward to hearing from you.

Sincerely,

Charles A. Lester, M.D.

CAL/slh

PERRY TAACA, M.D.

3801 N. CLASSEN BLVD. SUITE 100 • OKC, OK 73118 • PHONE: 405-557-1200 • FAX: 405-557-1977

12/10/04
Oklahoma Health Care Authority
Drug Utilization Review

Dear DUR Committee Members:
I have become aware that there may be a decision soon whether or not to require prior authorization of Detrol LA for Medicaid patients. I strongly urge committee members not to make this requirement for Detrol LA. It has been my experience that drugs that require prior approval creates a difficult, time consuming and at times unnecessary delay in providing treatment. My practice is currently limited exclusively to long term care facilities (nursing homes) and has been for the past 12 years. I am acutely aware of the costs attendant to the care of residents in these facilities. I personally review the medical record of each of my resident patients monthly. I review the medical administration record (MAR) in each nursing home for each resident monthly. This is done in addition to the required review done by consultant pharmacists. I take the information from the MAR with me when I make visits to my patients. The purpose is to be able to provide the best care. This record is invaluable when examining residents in a nursing home because so many of them are unable to give be accurate information about medications they are taking. When possible I discuss their medications with them but more often it is with the nursing staff who accompanies me. Part of providing the best care is to limit polypharmacy. Every effort s made monthly to eliminate unnecessary drugs. This is good for the patients at the same time helps control costs.

I mention all of this as background because there are times when trying to reduce costs by a restricted formulary actually comes at the detriment of the patient and ultimately an unintended consequence of increased expenses. In my opinion this would most likely occur if the use of Detrol LA is restricted. Episodes of incontinence in nursing home residents is a ubiquitous and costly happenstance. The aggregate cost of bedding changes, floor mopping, clothing changes, laundry, perineal treatment and extra nursing care is considerable. Unfortunately it is not uncommon for a resident to slip, fall and fracture a hip due to an incontinent episode. In my practice Detrol LA has demonstrably reduced incontinent episodes. This may be considered anecdotal but, I have been provided this feedback by my patients and by the nursing staff over many many months of use. It is my drug of choice when indicated both for its efficacy and comparative safety profile. Making it more difficult to use or causing delays in administering it I think is a mistake. While I am aware that generic Oxybutynin can be effective for incontinence episodes, it is against protocol for treatment in the elderly. The severity of the anticholinergic side effects and the multiple daily dosing make it difficult for patients to comply. Again I strongly urge committee members not to require prior authorization for this drug.

Perry T. Taaca M.D.

The University of Oklahoma
College of Medicine, Tulsa
DEPARTMENT OF INTERNAL MEDICINE

December 9, 2004

Ron Graham, D.Ph.
1113 N. Stonewall
P.O. Box 26901
Building ORIW 4403
Oklahoma City, OK 73190

RE: Long-acting anticholinergic products for overactive bladder

Dear Dr. Graham:

I understand that the Drug Utilization Review Board will be considering the issue of whether to discontinue the use of long acting anti-cholinergic products for treatment of overactive bladder. I am a geriatrician at the OU Tulsa campus as well as President of the Oklahoma Medical Directors Association. I am not speaking on behalf of the Association but mention it as a way of letting you know of my interest and activity with long term care facilities/patients.

I wish to urge that you not remove these long acting preparations from the formulary. Since the advent of these products I have seen a dramatic increase in tolerability and compliance with treatment. The elderly in general and nursing home patients in particular tend to carry a rather large anticholinergic burden from their medications. Many of their medications are not thought of as having anticholinergic effects but the cumulative effect is sizable. These products tend to exhibit a much lower side effect profile leading patients stick with them. They also have the advantage of less frequent dosing, decreasing some of the costs of medication administration in nursing facilities.

Please give strong consideration to leaving these medications on your formulary.

Thank you,

Jean Root, D.O.

Jean Root, D.O., M.P.H
Certified Medical Director
Associate Professor of Geriatrics

APPENDIX B

Pharmacotherapy Management Program
Quarterly Report
July – December 2004
Oklahoma Medicaid

	CLIENT PROFILES REVIEWED			PRIOR AUTHORIZATIONS				COMMUNICATIONS	
Month	New Clients	Established Clients	Incomplete Information	Total	Approved	Denied	Incomplete	Letters	Calls
July 2004	80	61	26	478	290	18	170	236	32
Aug 2004	102	77	27	681	381	24	276	348	100
Sept 2004	114	46	23	714	401	44	269	234	104
Oct 2004	99	35	20	711	437	55	219	349	73
Nov 2004	87	17	15	571	342	43	186	221	66
Dec 2004	94	49	13	638	382	61	205	348	89
Jan 2005	0	0	0	0	0	0	0	0	0
Feb 2005	0	0	0	0	0	0	0	0	0
March 2005	0	0	0	0	0	0	0	0	0
April 2005	0	0	0	0	0	0	0	0	0
May 2005	0	0	0	0	0	0	0	0	0
June 2005	0	0	0	0	0	0	0	0	0
Totals	576	285	124	3,793	2,233	245	1,325	1,736	464
1st Quarter	296	184	76	1,873	1,072	86	715	818	236
2nd Quarter	280	101	48	1,920	1,161	159	610	918	228
3rd Quarter	0	0	0	0	0	0	0	0	0
4th Quarter	0	0	0	0	0	0	0	0	0
Totals	576	285	124	3,793	2,233	245	1,325	1,736	464

Date Processed: Tuesday, January 04, 2005

Activity Audit for

December 01 2004 Through December 31 2004

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Smoking Cess. app.	Smoking Cess. den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	ARB app.	ARB den.	Anti-depressants app.	Anti-depressants den.	Daily Total
1	0	5	235	27	47	25	1	0	113	38	0	0	7	18	4	4	0	0	3	14	29	5	2	0	24	26	627
2	0	2	276	26	55	25	8	2	114	33	0	0	5	24	3	10	0	1	5	18	47	11	0	1	40	30	736
3	0	0	238	35	46	25	4	3	85	56	0	0	9	14	1	6	0	1	5	15	44	18	1	1	36	24	667
4	1	0	92	7	9	7	0	0	29	4	0	0	1	7	3	2	0	0	0	1	15	8	0	2	5	7	200
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	1	167	32	36	31	0	0	96	36	0	0	4	29	6	9	1	1	6	16	36	14	1	2	18	23	565
7	0	1	229	58	53	35	5	0	138	39	0	0	11	38	4	9	0	1	8	24	35	24	1	0	28	42	783
8	0	0	189	29	40	26	6	0	128	30	0	0	14	22	3	4	0	1	11	13	37	11	0	0	35	24	623
9	0	1	160	40	30	19	1	0	90	33	0	0	3	18	4	6	0	1	1	8	21	4	1	1	23	19	484
10	0	1	197	40	39	21	5	0	128	53	0	0	9	22	2	6	0	0	3	15	41	8	0	0	24	35	649
11	0	0	43	8	11	6	0	0	25	4	0	0	5	5	0	0	1	0	1	3	3	5	0	0	6	2	128
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	1	1	143	37	41	18	3	0	100	29	0	0	8	13	2	6	0	1	0	15	21	12	0	0	16	25	492
14	0	0	152	19	49	17	0	0	102	28	0	0	8	16	2	3	0	1	9	13	29	6	0	1	26	25	506
15	2	2	168	44	45	44	3	0	103	25	0	0	11	31	2	10	0	1	2	20	36	14	1	1	30	27	622
16	3	1	174	30	49	23	2	0	93	25	0	0	9	19	6	3	1	0	9	14	36	13	3	1	24	34	572
17	2	1	154	20	37	19	2	0	68	21	0	0	5	18	2	3	0	0	9	13	32	10	1	2	28	17	464
18	1	0	35	6	6	8	0	0	27	1	0	0	1	6	0	1	0	0	1	6	12	3	0	0	4	9	127
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	2	0	162	26	32	19	5	0	45	14	0	0	3	20	1	2	0	1	4	7	23	22	0	1	19	14	422
21	1	1	141	23	41	19	0	1	55	7	0	0	8	10	3	10	0	0	9	6	23	11	0	0	29	27	425
22	1	0	143	18	33	16	2	0	49	11	0	0	6	11	3	5	0	0	6	10	23	8	0	1	27	28	401
23	5	1	111	16	24	18	1	0	39	6	0	0	6	13	3	2	1	0	3	10	11	4	2	0	21	19	316
24	1	0	20	1	7	5	0	0	11	1	0	0	2	4	0	0	0	0	0	1	2	1	2	0	6	3	67
25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	1	1	126	20	19	12	0	0	26	12	0	0	5	6	1	2	0	0	5	10	14	10	1	1	17	21	310
28	2	0	123	26	26	7	1	0	44	22	0	0	5	8	4	4	0	0	6	12	31	3	0	1	20	10	355
29	1	1	157	17	41	21	3	0	53	21	0	0	5	16	1	4	1	0	10	11	32	11	3	2	26	17	454
30	1	0	85	7	30	13	3	1	31	8	0	0	5	9	2	6	0	0	5	4	20	10	2	0	14	13	269
31	0	0	22	7	10	5	0	0	13	1	0	0	2	3	0	0	0	0	0	0	9	1	0	0	0	1	74

Date Processed: Tuesday, January 04, 2005

Activity Audit for

December 01 2004 Through December 31 2004

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Smoking Cess. app.	Smoking Cess. den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	ARB app.	ARB den.	Anti-depressants app.	Anti-depressants den.	Daily Total
App.	25		3742		856		55		1805		0		157		62		5		121		662		21		546		
Den.		20		619		484		7		558		0		400		117		10		279		247		18		522	
Average Length of Approvals in Days	26		96		96		164		269		0		317		232		147		328		265		211		210		

Smoking Cessation		
	0 PA's for Zyban	0 Total PA's Approved
	0 PA's for Nicotine Patch	0 Unique RID's

Changes to existing PA's	41
Total (Previous Year)	7391

Monthly Totals

	Number	Percent of Total
Approved	9580	52.95%
Additional PA's	32	0.18%
SUPER PA's	2104	11.63%
Emergency PA's	0	0.00%
Duplicates	851	4.70%
Incompletes	1400	7.74%
Denied *	4126	22.80%
Total	18093	100.00%

Daily Average of 695.88 for 26 Days

*** Denial Codes**

762 = Lack of clinical information	31.63%
763 = Medication not eligible	2.13%
764 = Existing PA	15.95%
772 = Not qualified for requested Tier	13.45%

SUPER PA's

Early Refill Attempts	56600
Dosing Change	609
lost/stolen/broke	227
Other	184
wrong DS	98
Quantity vs. Days Supply	389

Changes to existing PA's: Backdates, changing units, end dates, etc.

Additional PA's: Done by the help desk (doctor letter responses, PA ran for the wrong person)

Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)

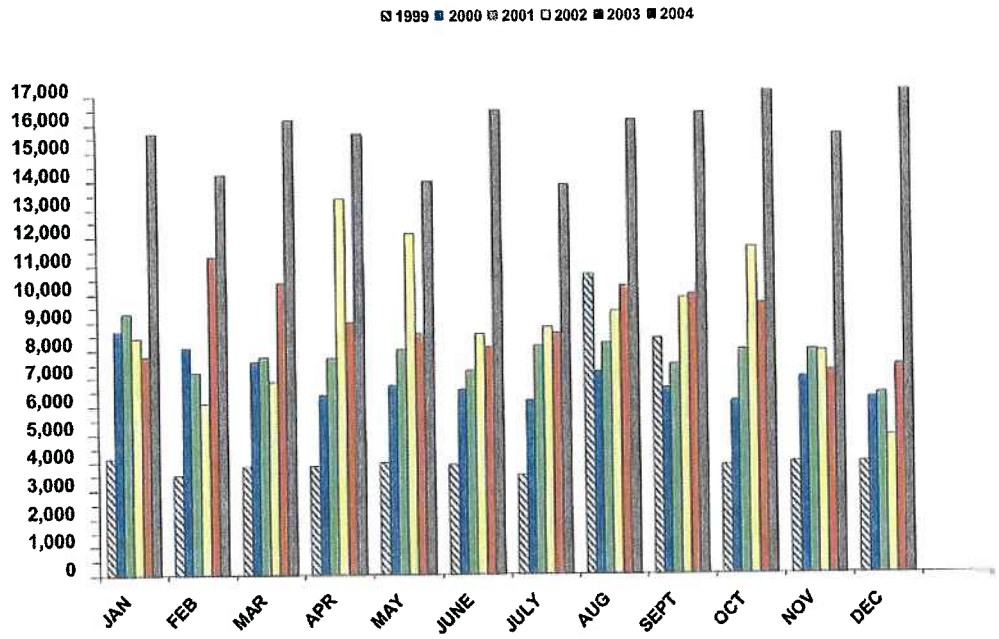
PRIOR AUTHORIZATION ACTIVITY AUDIT

Monthly Totals

MONTH	1999 Total *(approved/ duplicates/ denied)*	2000 Total *(approved/ duplicates/ denied)*	2001 Total *(approved/ duplicates/ denied)*	2002 Total *(approved/ duplicates/ denied)*	2003 Total *(approved/ duplicates/ denied)*	2004 Total *(approved/ duplicates/ denied)*
January	4,124	8,669	9,296	8,427	7,797	15,688
February	3,542	8,077	7,194	6,095	11,272	14,188
March	3,856	7,588	7,748	6,833	10,358	16,138
April	3,867	6,390	7,676	13,381	8,953	15,644
May	3,959	6,711	7,980	12,082	8,589	13,960
June	3,884	6,565	7,249	8,550	8,084	16,454
July	3,523	6,181	8,133	8,775	8,565	13,813
August	10,676	7,183	8,195	9,353	10,213	16,132
September	8,387	6,585	7,438	9,793	9,918	16,305
October	3,863	6,140	7,956	11,584	9,615	17,534
November	3,919	6,961	7,949	7,921	7,201	15,554
December	3,953	6,206	6,385	4,867	7,391	18,093
Calendar Year Total	**57,553**	**83,256**	**93,199**	**107,661**	**107,956**	**189,503**

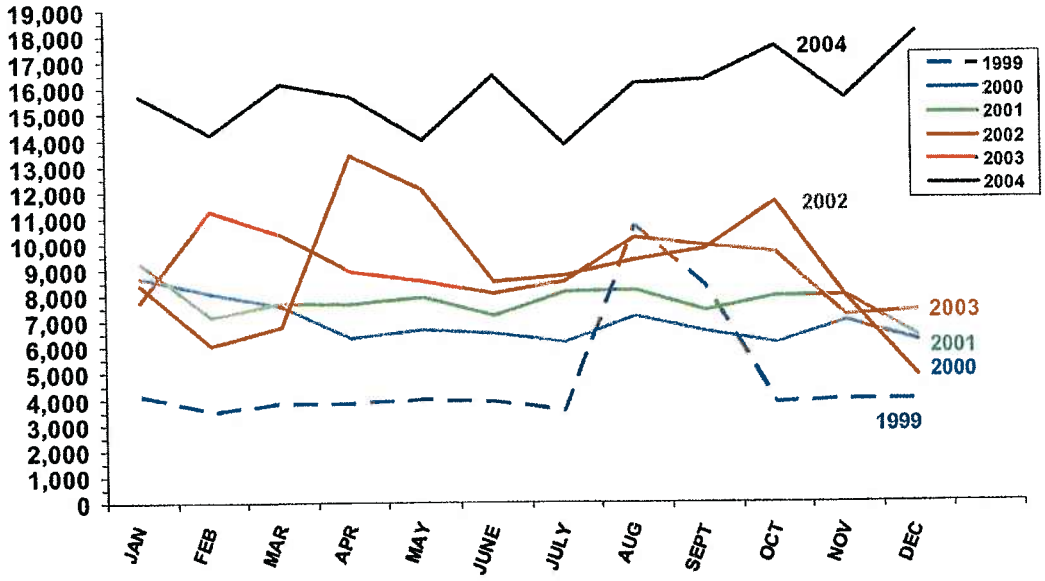
Monthly PA Activity

Calendar Years 2000-2004

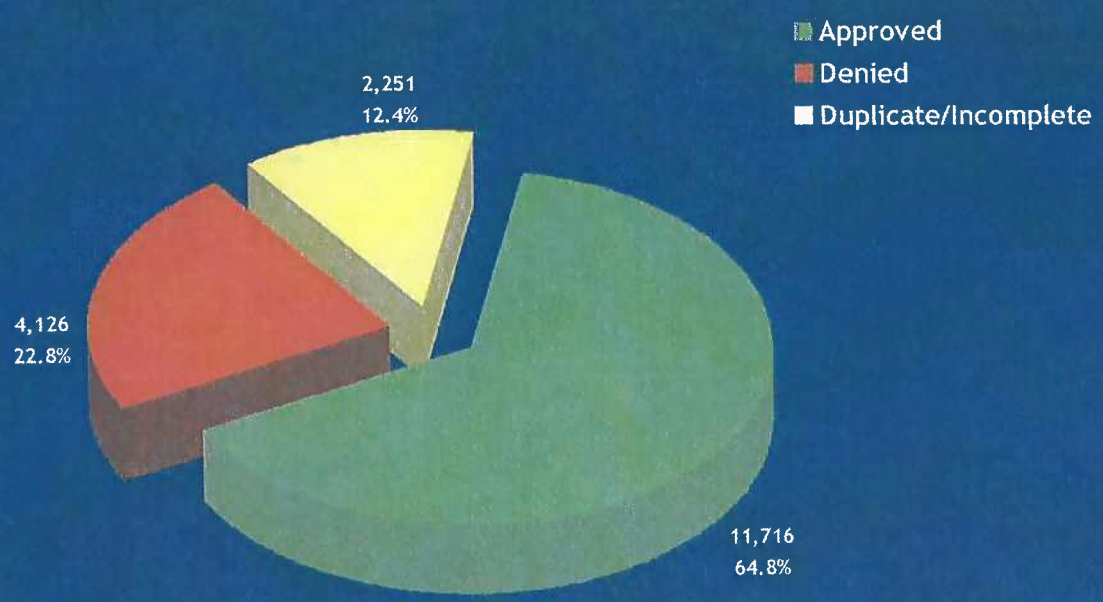


Monthly PA Activity

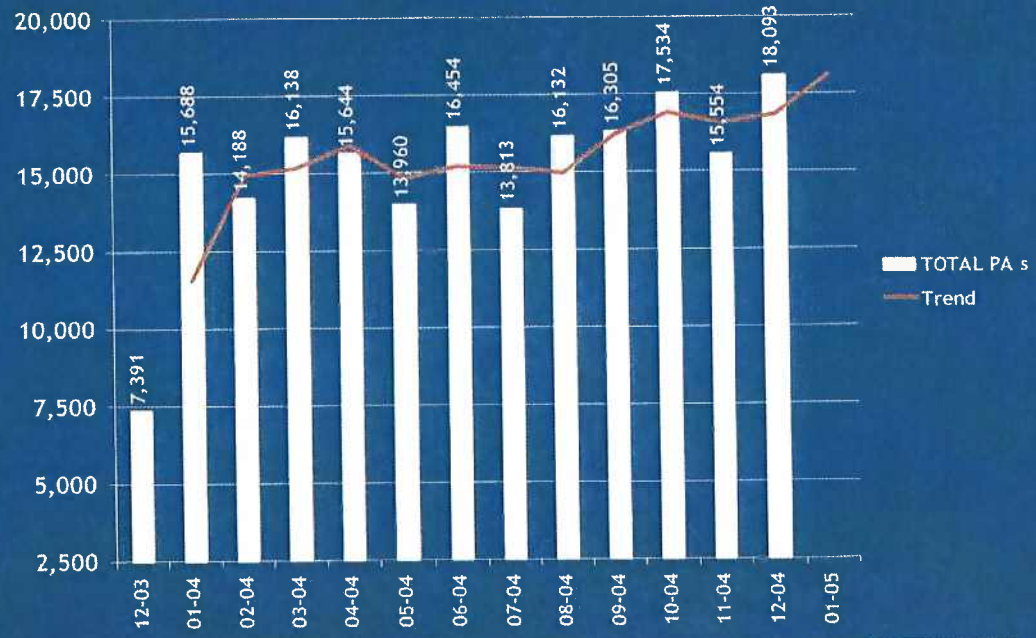
Calendar Years 2000-2004



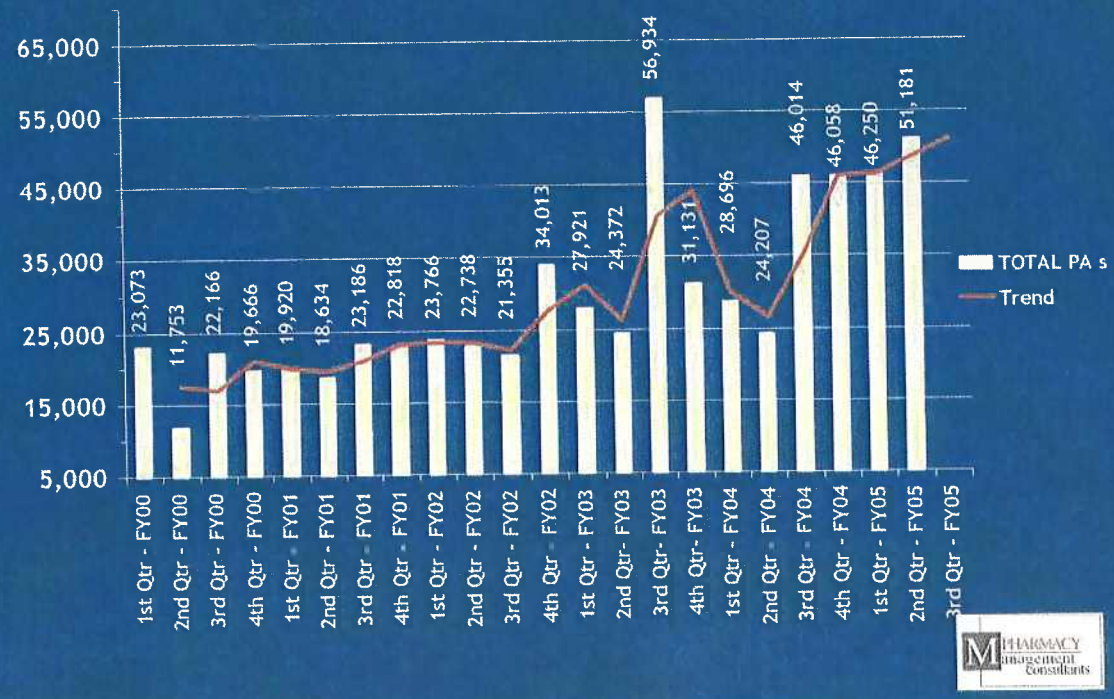
PRIOR AUTHORIZATION ACTIVITY REPORT
December 2004



PRIOR AUTHORIZATION REPORT
December 2003 - December 2004



PRIOR AUTHORIZATION QUARTERLY REPORT
FY00 through FY04
(July 1999 - December 2004)



CALL VOLUME -DECEMBER 2004

DECEMBER 04	CALLER					ISSUE					TYPE OF CALL					RESOLUTION							
																	Resolved						
	Call Volume	Physician	Pharmacies	Clients	Other	Eligibility	Claims	PA Issue	SMAC	Other	Regular	Callback	Proactive	ProDUR	Other	Helpdesk Resolved	Transferred Pharmacist	Transferred Supervisor	OHCA	Reversals/ Adjustments	EDS	Customer Service	Provider Contracts
1	1161	34	1040	70	17	270	499	146	0	246	1121	7	0	29	4	1117	6	2	1	2	0	24	9
2	937	31	815	64	27	93	479	160	1	204	886	16	2	31	2	902	5	4	0	0	1	15	10
3	912	13	787	87	25	184	372	151	0	205	878	9	1	17	7	871	10	4	1	0	2	11	13
4	223	0	220	3	0	33	124	21	0	45	212	0	0	11	0	221	0	0	0	0	0	2	0
5	56	0	51	3	2	12	26	4	0	14	52	2	0	2	0	55	0	0	0	0	0	0	1
6	1013	15	893	92	13	106	536	146	0	225	996	3	3	10	1	982	2	5	0	0	0	10	14
7	899	30	796	64	9	109	470	139	0	181	889	4	0	3	3	857	12	3	1	1	1	14	10
8	906	31	775	77	23	208	327	134	0	237	881	8	0	11	6	859	5	1	2	0	1	28	10
9	880	13	773	81	13	182	414	115	0	169	859	8	0	12	1	852	4	2	0	0	1	11	9
10	784	25	651	93	15	192	262	154	0	176	771	4	0	9	0	761	3	0	0	1	1	13	5
11	188	0	182	5	1	30	100	21	0	37	187	0	0	1	0	187	0	0	0	0	0	1	0
12	80	0	78	1	1	8	59	0	0	13	79	0	0	0	1	79	0	0	0	0	0	0	1
13	890	23	768	82	17	194	396	138	0	162	860	14	0	13	3	859	6	5	0	0	0	12	8
14	843	29	727	65	22	87	422	132	0	202	810	11	0	18	4	825	2	0	0	0	0	6	10
15	763	22	643	77	21	108	345	135	0	175	718	9	0	33	3	747	4	2	0	0	0	6	4
16	839	36	719	69	15	96	409	131	1	202	816	8	1	12	2	818	5	2	0	1	0	6	7
17	727	12	648	54	13	72	400	99	0	156	709	4	0	12	2	710	1	1	1	1	0	10	3
18	187	0	181	6	0	19	146	11	0	11	181	0	0	6	0	187	0	0	0	0	0	0	0
19	50	0	48	2	0	4	33	2	0	11	45	0	0	5	0	50	0	0	0	0	0	0	0
20	740	17	622	76	25	186	263	100	0	191	702	8	0	27	3	721	3	0	0	0	0	11	4
21	770	20	647	77	26	94	386	102	1	187	740	6	1	16	7	744	5	0	0	0	0	15	6
22	658	17	555	70	16	149	253	108	0	148	640	1	1	14	2	642	2	0	0	0	0	10	4
23	541	16	473	48	4	62	275	94	0	110	528	1	1	10	1	523	6	1	1	1	0	7	2
24	168	1	160	4	3	8	116	13	0	31	165	0	0	0	3	165	0	1	0	0	1	1	0
25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	752	13	639	79	21	81	430	103	1	137	710	15	0	25	2	731	3	4	0	1	1	11	1
28	679	11	589	71	8	86	390	56	0	147	667	2	0	7	3	655	2	0	0	0	1	15	6
29	652	18	567	56	11	176	248	94	0	133	635	7	0	10	0	636	4	0	0	0	0	9	3
30	620	7	557	47	9	191	210	84	0	135	607	0	0	13	0	598	7	0	0	0	0	7	8
31	285	1	273	11	0	18	216	21	0	29	284	0	0	1	0	282	0	0	0	0	0	3	0
Total	18,203	435	15,877	1,534	357	3,058	8,606	2,614	4	3,919	17,628	147	10	358	60	17,636	97	37	7	8	10	258	148
Percentage	100.00%	2.39%	87.22%	8.43%	1.96%	16.80%	47.28%	14.36%	0.02%	21.53%	96.84%	0.81%	0.05%	1.97%	0.33%	96.89%	0.53%	0.20%	0.04%	0.04%	0.05%	1.42%	0.81%

CALL VOLUME

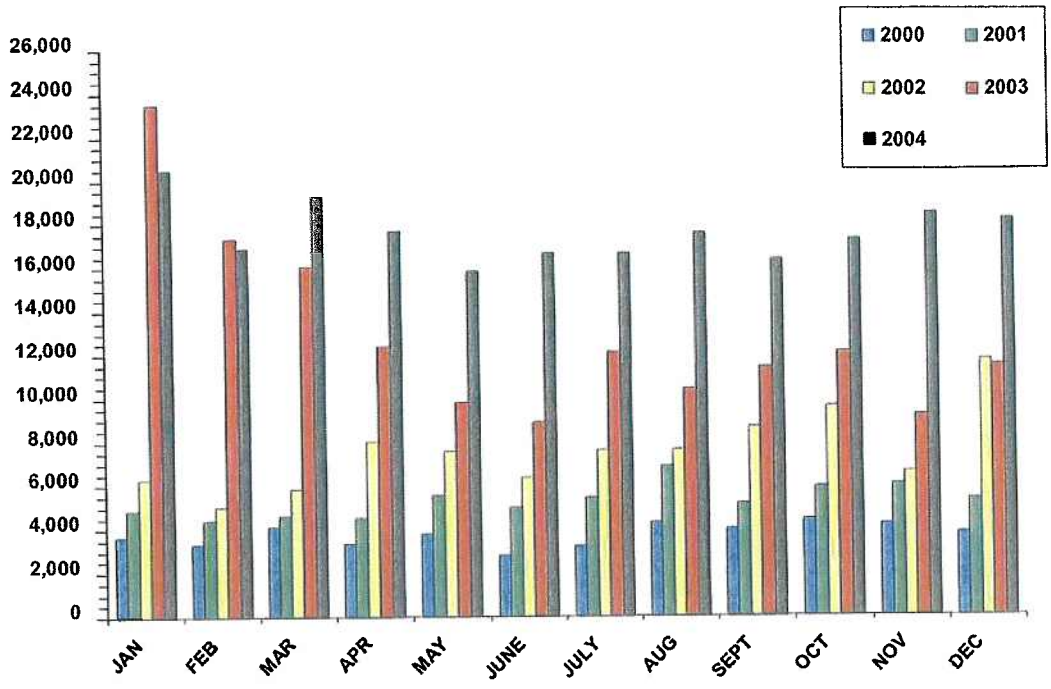
Monthly Totals

MONTH	1999 Total	2000 Total	2001 Total	2002 Total	2003 Total	2004 Total
January	* 0	3,697	4,905	6,295	23,499	20,498
February	* 0	3,335	4,393	5,049	17,354	16,857
March	* 0	4,157	4,668	5,858	16,081	19,232
April	* 0	3,337	4,556	8,047	12,378	17,660
May	* 0	3,804	5,540	7,586	9,836	15,828
June	* 0	2,820	4,982	6,368	8,917	16,634
July	* 0	3,242	5,465	7,651	12,126	16,662
August	3,883	4,333	6,881	7,629	10,454	17,563
September	2,360	4,015	5,145	8,664	11,449	16,373
October	1,963	4,398	5,912	9,608	12,102	17,300
November	1,721	4,216	6,011	6,627	9,178	18,477
December	2,475	3,804	5,314	11,710	11,461	18,203
Calendar Year Total	**12,402**	**45,158**	**63,772**	**91,092**	**154,835**	**211,287**

* Help Desk Call Center implemented in August 1999.

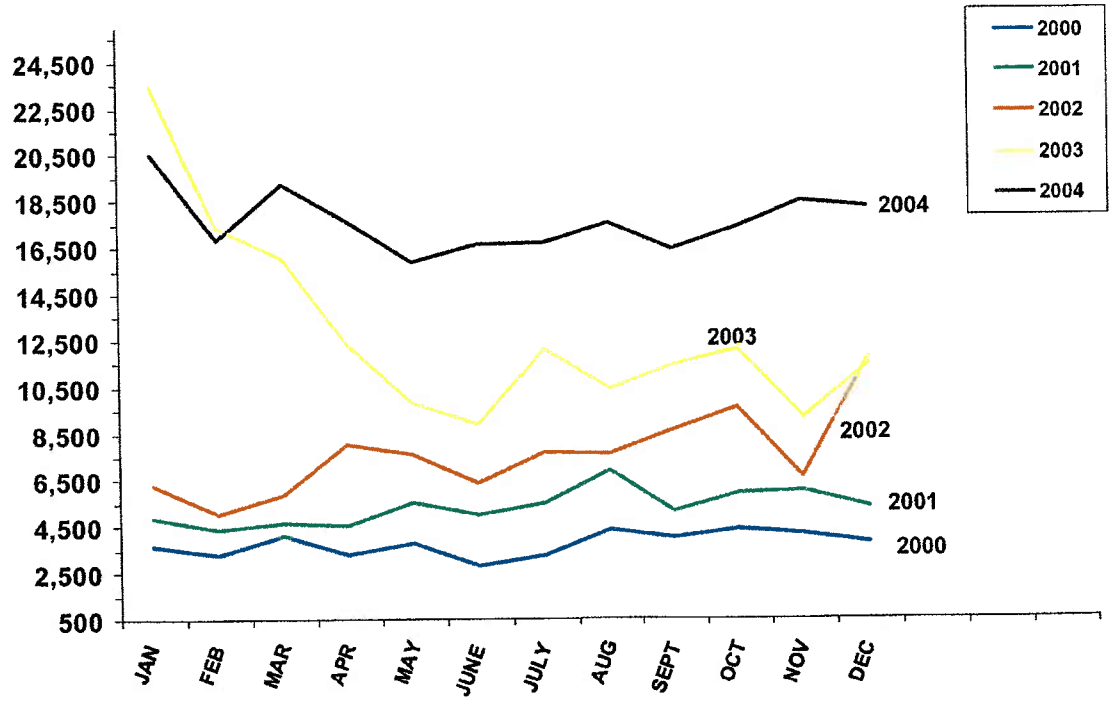
Monthly Call Volume

Calendar Years 2000-2004

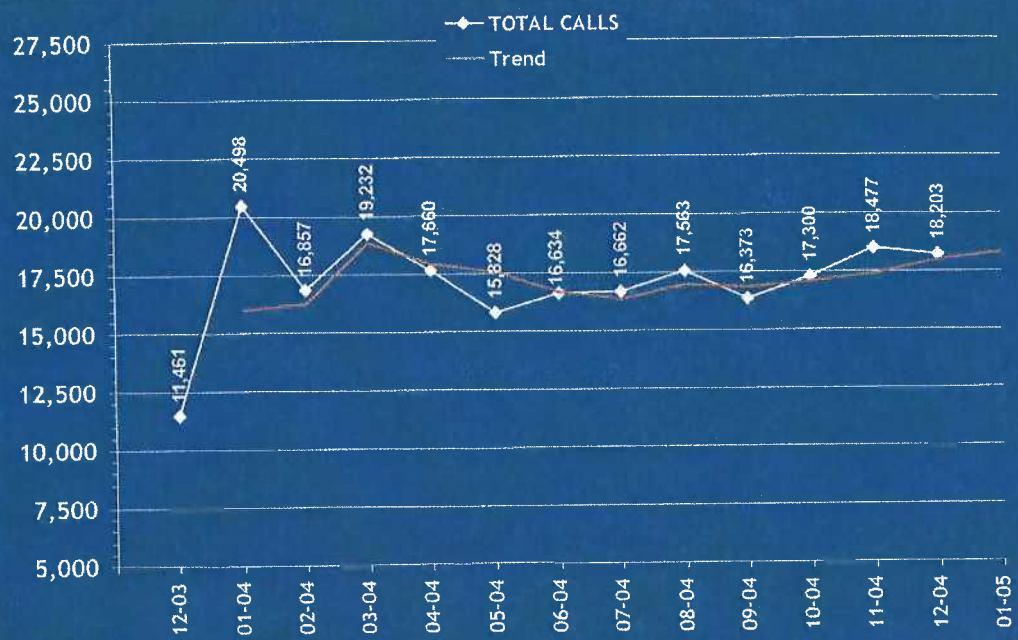


Monthly Call Volume

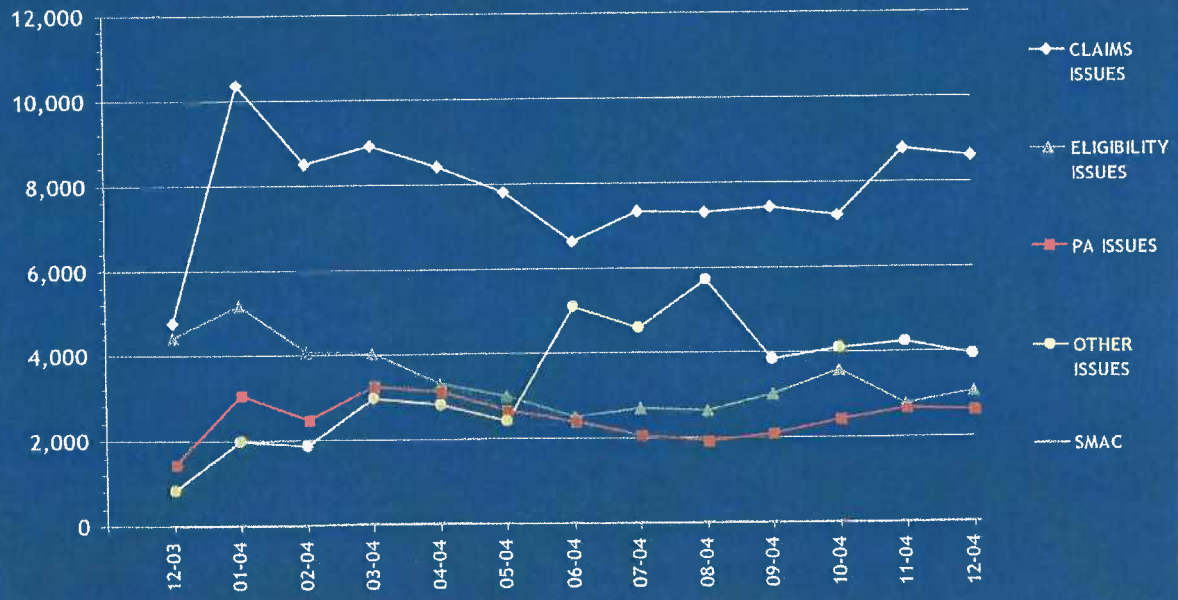
Calendar Years 2000-2004



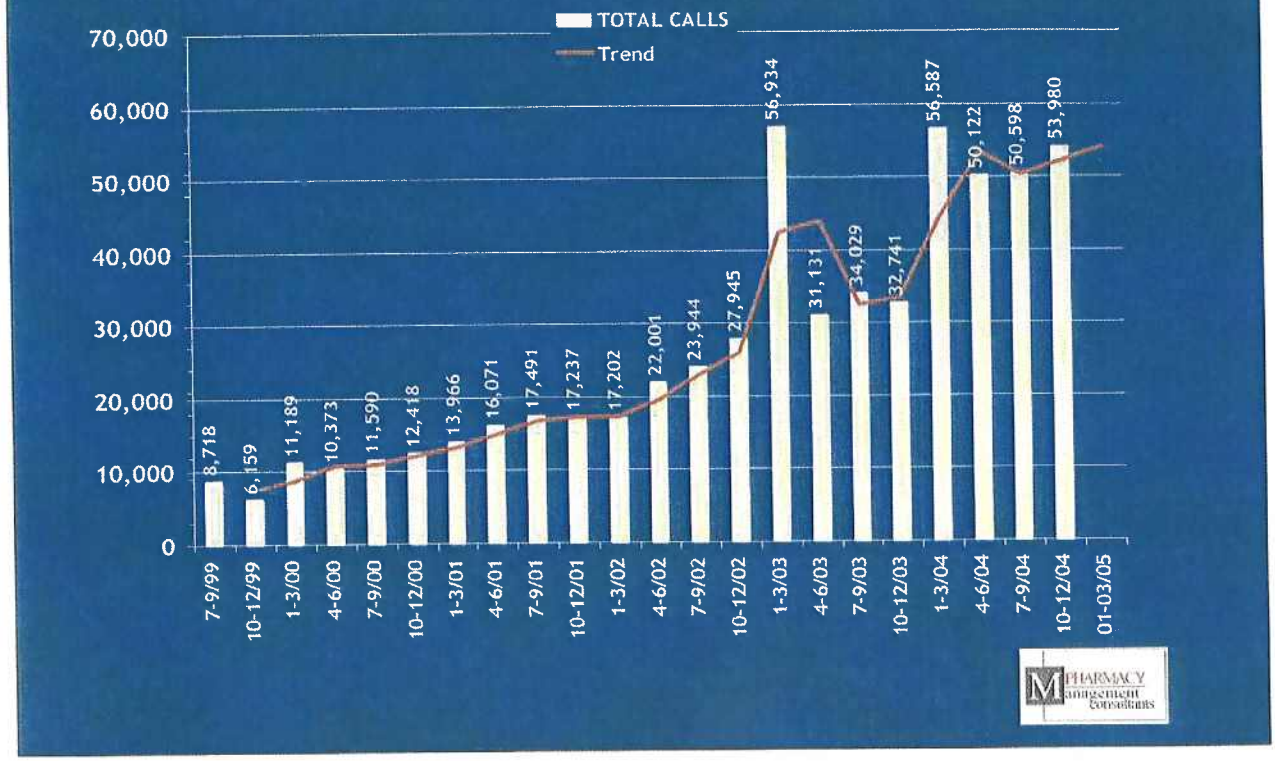
CALL VOLUME MONTHLY REPORT
December 2003 - December 2004



CALL VOLUME ISSUES
December 2003 - December 2004



CALL VOLUME QUARTERLY REPORT
July 1999 - December 2004



APPENDIX C

Update and Vote on Prior Authorization Status of Antidepressants
Oklahoma Medicaid
January 2005

Current Prior Authorization Criteria of SSRI

The following prior authorization criteria were approved by the Oklahoma Healthcare Authority in July of 2004. Beginning January 2005 the tier category is as follows:

Selective Serotonin Reuptake Inhibitors (SSRIs)	
*Tier One**	*Tier Two*
Fluoxetine (Prozac®)	Fluoxetine (Sarafem®)
Fluvoxamine (Luvox®)	
Paroxetine (Paxil®)	
Paroxetine (Paxil CR®)	
Paroxetine mesylate (Pexeva®)	
Sertraline (Zoloft®)	
Citalopram (Celexa®)	
Escitalopram (Lexapro®)	

*The tier one products per action of the DUR Board's vote were generic Fluoxetine, Paroxetine, and Fluvoxamine. All other products are in the tier one category due to the manufacturers' participation in the Supplemental Rebate Agreement.

Update on Safety Status of All Antidepressants

In September 2004 the FDA met with the committee on Psychopharmacologic Drugs and the Pediatric Advisory Committees in which several recommendations were made based upon conclusions the committees reached.

In summary, the members of the advisory committees[8]

- **Endorsed** FDA's approach to classifying and analyzing the suicidal events and behaviors observed in controlled clinical trials and expressed their view that the new analyses increased their confidence in the results;
- **Concluded** that the finding of an increased risk of suicidality in pediatric patients applied to all the drugs studied (Prozac, Zoloft, Remeron, Paxil, Effexor, Celexa Wellbutrin, Luvox and Serzone) in controlled clinical trials;
- **Recommended** that any warning related to an increased risk of suicidality in pediatric patients should be applied to all antidepressant drugs, including those that have not been studied in controlled clinical trials in pediatric patients, since the available data are not adequate to exclude any single medication from an increased risk;
- **Reached** a split decision (15-yes, 8-no) regarding recommending a "black-box" warning related to an increased risk for suicidality in pediatric patients for all antidepressant drugs;
- **Endorsed** a patient information sheet ("Medication Guide") for this class of drugs to be provided to the patient or their caregiver with every prescription;
- **Recommended** that the products not be contraindicated in this country because the Committees thought access to these therapies was important for those who could benefit; and
- **Recommended** that the results of controlled pediatric trials of depression be included in the labeling for antidepressant drugs.

The final wording for the Patient Medication Guide is expected to be completed sometime in January 2005. The information leaflet is to be included with every antidepressant prescription, regardless if it is a new prescription or a refill.

The black box warning will apply to all medications that are FDA approved for the treatment of depression. There is no deadline that the drug companies must meet as the process involves a series of steps that all manufacturers must follow. It is suspected to take upwards of several months for all manufacturers to complete the steps and start mass production of the revised product information. Below is a list of common antidepressants:

Tertiary amine tricyclics
Amitriptyline
Clomipramine (non-FDA)
Doxepine
Imipramine
Trimipramine

Secondary amine tricyclics
Desipramine
Nortriptyline
Protriptyline

Tetracyclics
Amoxapine
Maprotiline

SSRIs
Citalopram
Escitalopram
Fluoxetine
Fluvoxamine
Paroxetine
Sertraline

Dopamine-Norepinephrine Reuptake Inhibitors
Bupropion

Serotonin-Norepinephrine Re-uptake Inhibitors
Venlafaxine
Duloxetine

Serotonin Modulators
Nefazodone
Trazodone

Norepinephrine-Serotonin modulator
Mirtazapine

MAOIs
Phenelzine
Tranylcypromine

Current Safety Measures of Oklahoma Medicaid

In response to the FDA's warning on use of paroxetine in pediatric patients, the Drug Utilization Review Board approved a special prior authorization for paroxetine in October of 2003 for clients under 18 years of age. Clients who have been on paroxetine are allowed to continue without interruption. Criteria for approval would be based on two factors:

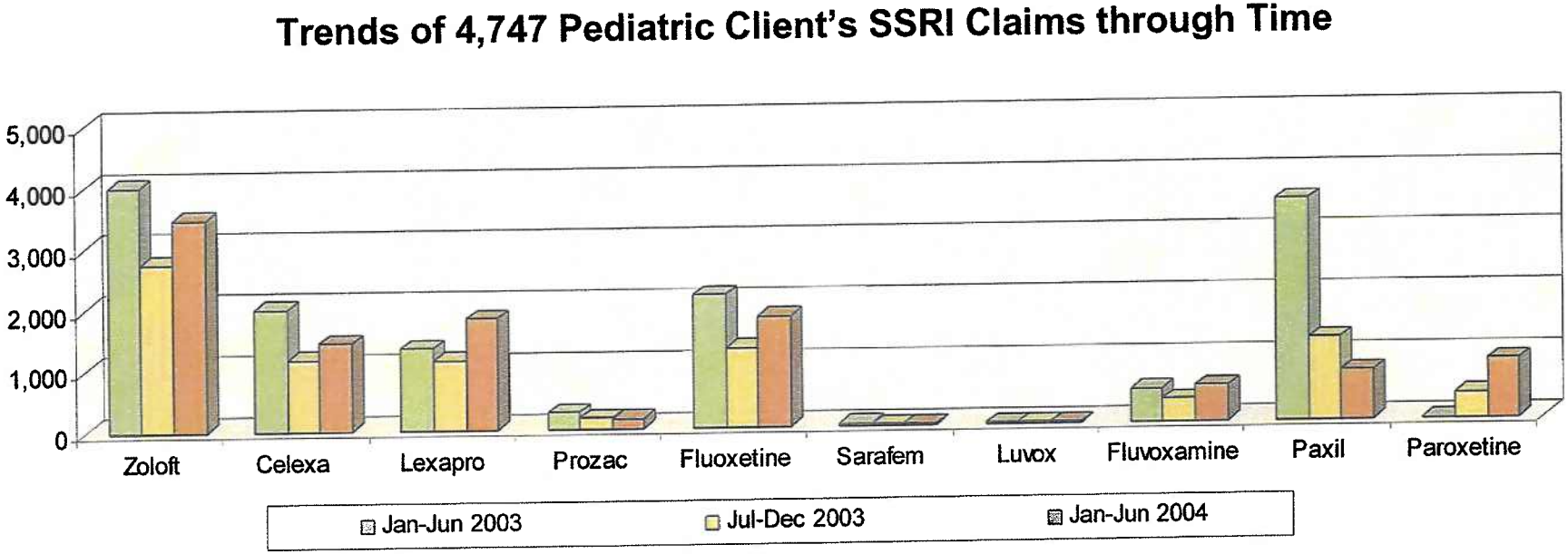
1. Both the following:
   - Documented failure of other therapy choices, and
   - Evaluation and initiation of the medication by a pediatric psychiatrist.
2. An acknowledgement from the prescriber that he/she is aware of the FDA warning and that the benefits of using the medication clearly outweigh the risks.

In light of recent conclusions reached by the examining and recommending bodies to the FDA, including the actions the FDA has taken, the DUR board may consider changing the current safety measures taken for the Oklahoma Medicaid population.

Pediatric SSRI Utilization

The following claims data has been compiled to give an overall picture of SSRI prescription claims activity during an 18 month period. From January through June of 2003 a total of 4,747clients in the Medicaid fee for service population had at least one paid claim for an SSRI. These same clients were followed from July of 2003 through July of 2004 to see how many were still getting an SSRI, and how the claims may have shifted between the products.

	Clients with Active Claims	Clients with SSRI Claims	All Clients with SSRI Claims
Jan-Jun 2003	4,747	4,747	4.747
Jul-Dec 2003	3,579	2,537	4,870
Jan-Jun 2004	3,332	2,046	7,059



Option One:

Apply a prior authorization to all antidepressants for clients under the age of 18 as it was concluded that the available data are not adequate to exclude any single medication from possessing an increased risk to the client.

The criteria will be altered to exclude the documented failure of other therapy choices as none can be deemed safer than the other in this aspect.

The prior authorization will mainly serve to ensure the prescription is prescribed by a pediatric psychiatrist, and that the prescriber is aware of the FDA warnings and risks.

Option Two:

Remove the existing prior authorization of paroxetine as it is no longer singled out by the FDA to exhibit risks to the pediatric population.

Recommendations:

The OU College of Pharmacy recommends Option Two. It appears the actions of the FDA, such as the black box warning requirement, implementation of the Patient Medication Guide, and all warnings issued in scientific and layman's language, may be sufficient in acknowledging the medical and patient communities of the risks associated with antidepressants.

References:

1 Website: **FDA Statement Regarding the Anti-Depressant Paxil for Pediatric Population.** Online. Internet. 2003. Available: www.fda.gov/bbs/topics/ANSWERS/2003/ANS01230.html

2. Website: **FDA Issues Public Health Advisory Entitled:Reports of Suicidality in Pediatric Patients Being Treated with Antidepressant Medications for Major Depressive Disorder.** Online. Internet. 2003. Available: www.fda.gov/bbs/topics/ANSWERS/2003/ANS01256.html

3. Website: **Reports on Suicidality in Pediatric Patients being Treated with Antidepressant Medications for Major Depressive Disorder.** Online. Internet. 2003. Available: www.fda.gov/cder/drug/advisory/mdd.htm

4. Website: **FDA Issues Publich Health Advisory on Cautions for Use of Antidepressants in Adults and Children.** Online. Internet. 2004. Available: www.fda.gov//bbs/topics/ANSWERS/2004/ANS01283.html

5. Website: **Worsening Depression and Suicidality in Patients Being Treated with Antidepressant Medications.** Online. Internet. 2004. Available: www.fda.gov/cder/drug/antidepressants/AntidepressanstPHA.htm

6. Website: **Background Information on the Suicidality Classification Project.** Online. Internet. 2004. Available: www.fda.gov/cder/drug/antidepressants/classificationProject.htm

7. Website: **Questions and Answers on Antidepressant Use in Children, Adolescents, and Adults.** Online. Internet. 2004. Available: www.fda.gov/cder/drug/antidepressants/Q&A_antidepressants.htm

8. Website: **FDA Statement on Recommendations of the Psychopharmacologic Drugs and Pediatric Advisory Committees.** Online. Internet. 2004. Available: www.fda.gov/bbs/topics/news/2004/NEW01116.html

9. Website: **FDA Launches a Multi-Pronged Strategy to Strengthem Safeguards for Children Treated With Antidepressant Medications.** Online. Internet. 2004. Available: www.fda.gov/bbs/topics/news/2004/NEW01124.html

10. Website: **Labeling Change Request Letter for Antidepressant Medications.** Online. Internet. 2004. Available: www.fda.gov/cder/drug/antidepressants/SSRIlabelChange.htm

11. Website: **Suicidality in Children and Adolescents Being Treated with Antidepressant Medications.** Online. Internet. 2004. Available: www.fda.gov/cder/drug/antidepressants/SSRIPHA2004.htm

APPENDIX D

Cymbalta® (duloxetine HCl)

Oklahoma Medicaid
January 2005

Manufacturer	Eli Lilly and Company
Pharmacologic Category	Selective Serotonin and Norepinephrine Reuptake Inhibitor (SSNRI); Dual-acting Antidepressant
Status	Prescription only

Pharmacological data
The active ingredient in Cymbalta® is duloxetine hydrochloride. Duloxetine is a potent inhibitor of serotonin and norephinephrine reuptake and a weak inhibitor of dopamine reuptake. The exact mechanisms which are linked to the antidepressant and pain relief activity are still unknown but it is thought to be due to the serotonergic and noradrenergic potentiation within the central nervous system. The enteric-coated pellets within in each capsule were designed to resist degradation within the acidic environment of the stomach. This formulation also allows for a delayed-release action during absorption.

Therapeutic indications
- Major Depressive Disorder (MDD)
- Diabetic Peripheral Neuropathy Pain (DPNP)
- Investigational Indications: Stress Urinary Incontinence and Treatment of Fibromyalgia pain

Bioavailability/pharmacokinetics
Absorption
- There is a 2-hour lag before absorption begins. Mean time to peak plasma levels occurs at 6 hours post dose.
- Steady-state plasma levels achieved after 3 days of dosing.
- Cymbalta® may be taken with or without food.
- Capsules should be swallowed whole and not crushed or chewed.

Distribution
- Duloxetine hydrochloride is approximately 90% protein bound.

Metabolism
- Elimination is primarily through the hepatic pathway involving 2D6 AND 1A2 liver enzymes.

Elimination
- Plasma half-life is 12 hours.
- 70% is excreted in the urine, mostly as metabolites.
- Remainder of dose is eliminated in the feces.

Dosage forms
Oral
- Capsules: 20mg, 30mg, and 60mg (contains enteric-coated pellets).

Dosage range
- Major Depressive Disorder (MDD)

- Recommended adult dose is 40mg/day (given as 20mg BID) up to 60mg/day (given as one 30mg capsule twice-daily or one 60mg capsule once-daily).

- Diabetic Peripheral Neuropathy Pain (DPNP)
  - Recommended adult dose is 60mg/day (given as one 60mg capsule daily).

Known adverse effects/toxicities
Side effects which occurred in 2% or more of the population in the pre-marketing clinical trial included: nausea, dry mouth, constipation, decreased appetite, fatigue, somnolence, and increased sweating. Reliable estimates of sexual dysfunction are difficult to obtain due to reluctance of patients or physicians to discuss such matters. No literature exists showing significant impact on systolic or diastolic blood pressure.

Special precautions
Worsening depression or suicide risk may occur especially at the initiation or during the treatment with antidepressants. This risk persists until remission is achieved during therapy. Patients should be closely monitored for increased occurrence of suicide ideation or behavior which may indicate a need for dosage reduction or therapy discontinuation. A gradual discontinuation of therapy is recommended rather than a sudden withdrawal from therapy due to adverse events which may occur during abrupt cessation of treatment.

It is not recommended to take monoamine oxidase inhibitors (MAOIs) in conjunction with Cymbalta® due to several reports of severe reactions which may occur while taking both a SNRI and a MAOI. A patient should not start a SNRI within 14-days of discontinuation of a MAOI and patients must allow 5 days to lapse after discontinuation of a SNRI before initiating MAOI therapy.

Cymbalta® has shown in pre-marketing clinical trials to increase levels of serum transaminase. It is recommended that patients with alcohol abuse and hepatic impairment should avoid treatment with Cymbalta®.

Patients with mood disorders should be aware of the risks of the activation of mania with the treatment of SNRIs.

Urinary hesitation may occur and patients should report any events of urinary difficulty or resistance.

Caution should be taken when patients have history of seizure disorders or narrow-angle glaucoma.

Contraindications
Cymbalta® is contraindicated in patients with known hypersensitivity to any components of the formulation.

Drug interactions

- Duloxetine hydrochloride is primarily metabolized by 1A2 and 2D6 hepatic isoenzymes. Medications that inhibit 1A2 and 2D6 may result in increase concentrations of duloxetine. Some quinolone antibiotics may have these effects and should be avoided.

- Duloxetine is also a moderate inhibitor of 2D6. This role does not affect its own metabolism but medications metabolized by this isoenzyme should be used cautiously.
- Drugs that increase in gastric acidity or delay gastric emptying may lead to increase in absorption resulting in increased levels of duloxetine.

Table 1: Other Antidepressants for treatment of Major Depressive Disorder

	Estimated Acquisition Cost (EAC) Per Unit	State Maximum Allowable Cost (SMAC)	Daily Dose (Initial)	Monthly Dose* (30 day supply)
Selective Serotonin and Norepinephrine Reuptake Inhibitors (SSNRI)				
Cymbalta® 20mg	$2.79	$0.00	40mg	$167.40
Cymbalta® 30mg	$3.14	$0.00	60mg	$188.40
Cymbalta® 60mg	$3.14	$0.00	60mg	$94.20
Effexor XR® 37.5mg	$2.68	$0.00	37.5mg	$80.40
Effexor XR® 75mg	$3.00	$0.00	75mg	$90.00
Effexor XR® 150mg	$3.27	$0.00	150mg	$98.01
Effexor® 25mg	$1.61	$0.00	75mg	$144.90
Effexor® 37.5mg	$1.66	$0.00	75mg	$99.60
Effexor® 50mg	$1.71	$0.00	75mg	$76.95
Effexor® 75mg	$1.81	$0.00	75mg	$54.30
Effexor® 100mg	$1.92	$0.00	100mg	$57.60
Selective Alpha-2 Antagonist**				
Remeron® 15mg	$2.77	$0.25	15mg	$7.50
Remeron® 30mg	$2.86	$0.38	30mg	$11.40
Remeron® 45mg	$2.91	$0.52	45mg	$15.60
Remeron® 15mg Soltab	$2.54	$0.00	15mg	$76.20
Remeron® 30mg Soltab	$2.62	$0.00	30mg	$78.60
Remeron® 45mg Soltab	$2.79	$0.00	45mg	$83.70
Mirtazapine 15mg Soltab	$2.29	$0.00	15mg	$68.70
Mirtazapine 30mg Soltab	$2.35	$0.00	30mg	$70.50
Mirtazapine 45mg Soltab	$2.50	$0.00	45mg	$75.00
Selective Dopamine Reuptake Inhibitor***				
Wellbutrin® 75mg	$1.15	$0.21	300mg	$25.20
Wellbutrin® 100mg	$1.53	$0.31	300mg	$27.90
Wellbutrin® 100mg SR	$1.86	$1.31	300mg	$117.90
Wellbutrin® 150mg SR	$1.99	$1.51	300mg	$90.60
Wellbutrin® 200mg SR	$3.69	$0.00	400mg	$221.40
Wellbutrin® 150mg XL	$2.82	$0.00	150mg	$84.60
Wellbutrin® 300mg XL	$3.73	$0.00	300mg	$111.90
Selective Serotonin Reuptake Inhibitors/Antagonist (SARI)**				
Serzone® 50mg	$1.54	$0.29	200mg	$34.80
Serzone® 100mg	$1.58	$0.32	200mg	$19.20
Serzone® 150mg	$1.61	$0.32	300mg	$19.20
Serzone® 200mg	$1.64	$0.33	200mg	$9.90
Serzone® 250mg	$1.67	$0.34	500mg	$20.40

*SMAC pricing used where appropriate and indicates generic availability. No rebate information was incorporated.

**Bristol-Myers Squibb announced discontinuation of sales of Serzone® 06/14/2004, generic still available.

***Some norepinephrine reuptake inhibition.

****Increase release of norepinephrine and serotonin.

Recommendations

The college of pharmacy recommends consideration of a prior authorization category similar to the SSRIs (see table 1). In the meantime, the college of pharmacy intends to further evaluate and monitor the use of these newer antidepressants pending new clinical literature and newly approved indications.

References

1 Cymbalta® Prescribing Information. http://www.cymbalta.com Eli Lily and Company August 2004.

2. Arnold LM, Lu Y, Crofford LJ, et al. A double-blind multi-center trial comparing duloxetine to placebo in the treatment of fibromyalgia with or without major depressive disorder. Poster presented at: The American College of Neuropsycholopharmacology; December 7-11, 2003; Puerto Rico.
3. Andersson KE, Pehrson R. CNS involvement in overactive bladder: pathophysiology and opportunities for pharmacological intervention. Drugs. 2003; 63:2595-2611.
4. Eli Lilly and Company. FDA approves Antidepressant *Cymbalta* for treatment of pain caused by diabetic peripheral neuropathy, which affects up to 5 million Americans. September 7, 2004. Available at: http://newsroom.lilly.com/news/product/2004-09-07_cymbalta_fda_apprvl_dpn_pfv.html
5. Lesher BA. New Drug: *Cymbalta* (duloxetine). *Pharmacist's Letter/Prescriber's Letter* 2004; 20:200901.
6. Lexi-Comp Online™ http://www.crlonline.com Lexi-Comp December 2004.

APPENDIX E

30 DAY NOTICE OF INTENT TO PRIOR AUTHORIZE BLADDER CONTROL DRUGS

Oklahoma Medicaid – January 2005

Demographic information - Clients 65 years and over

Clients on Bladder Control Drugs

Age	Female	Male	Total
0 to 9	164	130	294
10 to 19	184	103	287
20 to 34	243	111	354
35 to 49	619	201	820
50 to 64	988	224	1212
65 to 79	1514	312	1826
80 to 94	1634	252	1886
95 and over	138	13	151
FY 04 Total	**5484**	**1346**	**6830**

Clients on Bladder control drugs who are in Nursing Homes

Age	Female	Male	Total
0 to 9	0	0	0
10 to 19	1	1	2
20 to 34	9	20	29
35 to 49	67	49	116
50 to 64	218	93	311
65 to 79	576	180	756
80 to 94	992	170	1162
95 and over	110	9	119
FY 04 Total	**1973**	**522**	**2495**

Clients, ≥65 years, on Bladder Control Drug

Age	Female	Male	Total
65 to 79	1514	312	1826
80 to 94	1634	252	1886
95 and over	138	13	151
FY 04 Total	**3286**	**577**	**3863**

Clients on bladder Control drugs, who are in Nursing homes and are ≥65 years

Age	Female	Male	Total
65 to 79	576	180	756
80 to 94	992	170	1162
95 and over	110	9	119
FY 04 Total	**1678**	**359**	**2037**

Comparison of Utilization by Clients on Bladder Control Drugs

Population	# of Clients	Total Claims	Total Units	Total Days	Total Cost
General	6,830	34,465	1,739,506	1,180,575	$3,214,042.21
General - ≥ 65 yrs	3,863	22,155	972,410	742,631	$2,062,558.06
Nursing Home	2,495	17,884	700,160	520,932	$1,480,933.12
Nursing Home - ≥ 65 yrs	2,037	14,489	546,245	420,354	$1,186,609.59

Recommendations

The College of Pharmacy recommends prior authorizing this class of drugs utilizing the PBPA program. Authorization will be given for 1 year.

- Tier-1 – Detrol, Oxybutynin, hyoscyamine*
- Tier-2 - Detrol LA, Ditropan XL, Flavoxate, Oxytrol, Sanctura, VESIcare

*hyoscyamine can be used as adjuvant therapy only; by itself, it will not count toward a tier-2

Prior authorization criteria:

In order to get a tier-2 drug, client must meet one of the following criteria:

- tier-1 drug failure (i.e. inadequate clinical response or adverse effect), or
- contraindication to the tier-1 drugs , or
- already stabilized on the tier-2 drug, or
- using the tier-2 drug for a unique indication which the tier-1 drugs lack

Potential Economic Impact

Based on a future projected 10 % shift to the recommended tier-1 products a net annualized cost savings and administrative costs have been calculated.

Option 1. *If all clients are included in the PBPA:*

Estimated Annual Savings (minus rebate and dispensing fees):	$ 259,242.52
Potential Annual Administrative Cost*:	46,199.14
Total Net Plan Savings:	**$ 213,043.38**

Option 2. *If all clients over 65 years of age are EXCLUDED from the PBPA:*

Estimated Annual Savings (minus rebate and dispensing fees):	$ 108,413.04
Potential Annual Administrative Cost*:	18,313.64
Total Net Plan Savings:	**$ 90,099.40**

Option 3. *If all clients over 65 years of age* in a care facility *are EXCLUDED from the PBPA:*

Estimated Annual Savings (minus rebate and dispensing fees):	$ 178,006.25
Potential Annual Administrative Cost*:	31,906.20
Total Net Plan Savings:	**$ 146,100.05**

* The average cost for processing petitions is calculated at $6.75 per petition with the maximum cost at $12.97 per petition. The maximum cost was used in the estimation of administrative costs.

APPENDIX F

Prior Authorization Annual Review - Fiscal Year 2004

Anxiolytics/Hypnotics
Oklahoma Medicaid
January 2005

Definition of Prior Authorization Category for FY '04

With respect to the anxiolytic/hypnotic medications:

- Clients may receive two medications in this category if one is used during the day for one diagnosis and the other is used at night as a hypnotic agent; or if they are using two different strengths to reach a target dose not available in a single unit.

- Clarification of dosing schedule and diagnosis are important to assure that the client is not receiving duplicate therapy (e.g. an anxiolytic and hypnotic both dosed at bedtime).

- Additional information regarding recent attempts at dose reductions should be requested on recurrent petitions for high dose anxiolytics and hypnotic medications.

Utilization

35,249 clients received benzodiazepines/hypnotics through the Medicaid fee-for-service program for fiscal year 2004.

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Alprazolam 0.25mg	10,901	625,396	258,262	2.42	$68,072.47	3,694	$0.26
Xanax 0.25mg	28	1,990	737	2.70	$1,715.90	11	$2.33
Alprazolam 0.5mg	15,980	1,050,633	405,365	2.59	$113,894.03	5254	$0.28
Xanax 0.5mg	66	4,911	1,835	2.68	$4,254.34	25	$2.32
Alprazolam 1mg	14,770	1,183,819	409,240	2.89	$123,930.09	4,172	$0.30
Xanax 1mg	90	6,918	2,792	2.48	$9,737.32	29	$3.49
Alprazolam 2mg	4,725	412,456	130,836	3.15	$69,743.39	1,338	$0.53
Xanax 2mg	16	1,562	462	3.38	$3,438.29	6	$7.44
Alprazolam 1mg/ml	2	60	40	1.50	$122.84	2	$3.07
Xanax XR 0.5mg	2	150	60	2.50	$290.10	2	$4.84
Xanax XR 1mg	12	398	398	1.00	$962.70	4	$2.42
Xanax XR 2mg	20	846	641	1.32	$2,620.04	9	$4.09
Xanax XR 3mg	13	568	373	1.52	$2,689.60	4	$7.21
CDP 5mg	302	16,895	7,483	2.26	$2,462.73	78	$0.33
CDP 10mg	1,118	78,496	29,128	2.69	$8,346.52	333	$0.29
Librium 10mg	15	520	245	2.12	$332.42	3	$1.36
CDP 25mg	772	54,925	19,192	2.86	$6,948.51	280	$0.36
Librium 25mg	5	210	150	1.40	$338.14	2	$2.25
Librium Inj 100mg	1	50	12	4.17	$1,159.90	1	$96.66

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Cloraze DIP 3.75mg	1,496	101,942	41,388	2.46	$20,589.01	363	$0.50
Tranxene 3.75mg	7	380	235	1.62	$584.74	5	$2.49
Cloraze Dip 7.5mg	1,566	108,953	45,780	2.38	$25,311.94	395	$0.55
Tranxene 7.5mg	25	2,240	731	3.06	$4,932.99	6	$6.75
Cloraze Dip 15mg	302	22,814	9,227	2.47	$19,724.20	60	$2.14
Tranxene T 15mg	24	2,400	792	3.03	$8,677.40	2	$10.96
Tranxene-S 22.5mg	15	1,710	442	3.87	$12,278.03	2	$27.78
Diazepam 2mg	1,918	99,174	40,398	2.45	$10,573.65	790	$0.26
Diazepam 5mg	8,827	489,714	206,107	2.38	$46,963.11	3,447	$0.23
Diazepam 10mg	8,232	577,882	212,117	2.72	$58,139.51	2,661	$0.27
Diazepam 5mg/ml con	15	925	377	2.45	$802.22	6	$2.13
Diazepam 1mg/ml sol	189	38,819	3,269	11.87	$4,674.56	67	$1.43
Diazepam 5mg/ml inj	193	1,973	781	2.52	$2,234.07	108	$2.86
Ativan 0.5mg	36	2,083	1,019	2.04	$1,555.87	15	$1.53
Lorazepam 0.5mg	12,980	701,142	299,821	2.34	$120,611.80	15	$0.40
Ativan 1mg	54	4,298	1,544	2.78	$3,712.24	24	$2.40
Lorazepam 1mg	11,885	714,562	283,562	2.52	$131,439.84	3,765	$0.46
Ativan 2mg	11	325	278	1.17	$912.28	6	$3.28
Lorazepam 2mg	3,258	210,702	83,562	2.52	$50,842.67	995	$0.61
Lorazepam 2m/ml Con	134	3,341	1,902	1.76	$5,053.37	79	$2.66
Ativan 2mg/ml inj	867	4,613	2,187	2.11	$27,856.89	445	$12.74
Lorazepam 2mg/ml inj	358	3,436	1,485	2.31	$10,304.87	215	$6.94
Lorazepam 4mg/ml	1	4	4	1.00	$43.66	1	$10.92
Oxazepam 10mg	445	32,784	12,024	2.73	$11,683.01	100	$0.97
Oxazepam 15mg	415	32,798	11,773	2.78	$17,348.30	94	$1.47
Oxazepam 30mg	76	5,738	2,136	2.68	$5,356.77	16	$2.51
Serax 15mg	4	402	104	3.86	$467.21	2	$4.49
Estazolam 1mg	169	4,765	4,766	1.00	$2,218.35	41	$0.46
Prosom 1mg	2	45	45	1.00	$20.61	2	$0.46
Estazolam 2mg	172	5,753	5,474	1.05	$2,802.08	47	$0.51
Prosom 2mg	1	30	30	1.00	$14.29	1	$0.48
Flurazepam 15mg	128	4,041	3,144	1.28	$804.85	57	$0.25
Flurazepam 30mg	297	9,718	9,159	1.06	$2,035.21	112	$0.22
Doral 7.5mg	4	120	120	1.00	$363.84	1	$3.03
Doral 15mg	5	330	330	1.00	$1,040.25	2	$3.15
Restoril 7.5mg	1,147	34,126	31,249	1.09	$74,778.36	368	$2.39
Temazepam 7.5	9	344	232	1.48	$229.96	9	$1.00
Restoril 15mg	14	435	353	1.23	$384.82	14	$1.09
Temazepam 15mg	6,602	216,189	189,041	1.14	$44,677.89	2,491	$0.24
Restoril 30mg	29	869	869	1.00	$1,718.73	13	$1.98
Temazepam 30mg	6,016	198,152	189,771	1.04	$46,693.68	2,123	$0.25
Triazolam 0.125mg	78	2,330	2,001	1.16	$736.72	40	$0.37
Halcion 0.25mg	34	1,504	1,043	1.44	$1,933.21	9	$1.85
Triazolam 0.25mg	742	23,720	17,308	1.37	$7,252.61	317	$0.42
Sonata 5mg	258	7,471	6,805	1.09	$16,105.17	110	$2.37
Sonata 10mg	1,049	35,208	29,975	1.17	$91,709.27	395	$3.06
Ambien 5mg	7,898	226,821	212,813	1.06	$505,938.95	2,817	$2.38
Ambien 10mg	14,979	456,467	446,008	1.02	$1,236,749.78	4,776	$2.77
Total	**141,804**	**7,834,801**	**3,680,832**		**$3,061,942.17**	**35,249***	**$0.83****

*Total unduplicated clients for FY04.
**Total cost/total days.

Total Cost FY '04	**$3,061,942.17**
Total Cost FY '03	*$2,613,317.69*
Total Claims FY '04	**141,804**
Total Claims FY '03	*112,777*
Total Clients FY '04	**35,249**
Total Clients FY '03	*28,183*
Per Diem FY '04	**$0.83**
Per Diem FY '03	*$0.90*

Total petitions submitted in for this category during specified time period:

Approved	31,684
Denied	4,514
Incomplete	1,670
Supers	35

Claims were reviewed to determine the age/gender of the clients.

FY '04

Age	Female	Male	Totals
0 to 9	297	336	633
10 to 19	1127	755	1882
20 to 34	3722	1007	4729
35 to 49	5567	2645	8212
50 to 64	5010	2433	7443
65 to 79	5288	1729	7017
80 to 94	4094	853	4947
95 and Over	354	32	386
Totals	**25,459**	**9,790**	**35,249**

FY '03

Age	Female	Male	Totals
0 to 9	162	225	387
10 to 19	736	522	1258
20 to 34	2408	787	3195
35 to 49	3691	2099	5790
50 to 64	3652	1818	5470
65 to 79	4962	1668	6630
80 to 94	4140	900	5040
95 and Over	378	35	413
Totals	**20,129**	**8,054**	**28,183**

Recommendations

The college of pharmacy recommends the following changes to the current criteria for this category:

- Implement quantity limits on the category as follows:
  - Anxiolytics – maximum of four units (doses) daily,
  - Hypnotics – one to two units daily based on FDA approved dosing (currently only Ambien® and Sonata® have quantity limits in place).

- Update Therapeutic Duplication ProDUR module to limit duplications.

APPENDIX G

30 Day Notice of Intent to Prior Authorize Lunesta® (eszopiclone)

Oklahoma Medicaid
January 2005

Manufacturer	Sepracor Inc
Classification	Nonbenzodiazepine hypnotic Prescription only, Schedule IV

Pharmacological data

The active ingredient in Lunesta® is eszopiclone. Eszopiclone is a nonbenzodiazepine hypnotic that is a pyrrolopyrazine derivarive of the cyclopyrrolone class. The chemical structure is unrelated to pyrazolopyrimidines, imidazopyridines, benzodiazepines, barbiturates, or other drugs with known hypnotic properties. The precise mechanism of action is unknown but is thought to be the result of interaction with the GABA-receptor complexes at binding domains located close to or allosterically coupled to benzodiazepine receptors.

Therapeutic indications

- Insomnia
- Sleep latency
- Sleep maintenance

Bioavailability/pharmacokinetics

Absorption

- Rapidly absorbed after oral administration
- Peak plasma concentrations achieved within approximately 1 hr

Distribution

- Weakly bound to plasma protein (52-59%)
- Large free fraction suggests that disposition should not be affectred by drug-drug interactions due to protein binging
- Blood-to-plasma ratio is less than 1, indicating no red blood cell selectivity

Metabolism

- Extensively metabolized by oxidation and demethylation
- Primary plasma metabolites are (S)-zopiclone-N-oxide and (S)-N-desmethyl sopiclone
- (S)-N-desmethyl sopiclone binds GABA receptors with lower potency than eszopiclone
- (S)-zopiclone-N-oxide has no significant binding to the GABA receptors
- CYP3A4 and CYP2E1 are involved in metabolism of eszopiclone
- Eszopiclone shows no inhibitory potential on CYP450 1A2, 2A6, 2C9, 2C19, 2D6, 2E1, AND 3A4 in cryopreserved human hepatocytes

Elimination

- Mean T ½ of approximately 6 hours
- Up to 75% of racemic zopiclone is excreted primarily as metaolites in the urine
- Less than 10% of parent drug is excreted in the urine

Dosage forms

Oral

- Tablets: 1mg, 2mg, and 3mg

Dosage range

Pediatric Use:

Under age 18, safety and efficacy have not been established.

Adults:

Starting at 2mg and increasing to 3mg or starting at 3mg (more effective for sleep).

Elderly (65 and over) Use:

Starting at 1mg not to exceed 2mg

Hepatic:

Starting at 1mg and used with caution with severe impairment

CYP3A4 Inhibitors

Starting dose should not exceed 1mg, can be increased to 2mg if needed.

Known adverse effects/toxicities

Side effects that occurred in 2% or more of the population in pre-marketing clinical trial included:

- Adult population: viral infection, dry mouth, dizziness, hallucinations, infection, rash, and unpleasant taste.
- Elderly adults: pain, dry mouth, and unpleasant taste.
- Patients have recovered from overdoses of 340mg (56 times the maximum recommended dose).

Special precautions

Take Lunesta immediately before bedtime. Taking sedative/hypnotic while still mobile can result in short-term memory impairment, hallucinations, impaired coordination, dizziness and lightheadedness which could result in a fall.

Contraindications

- None known.

Drug interactions

- Eszopiclone is metabolizedby CYP3A4 and CYP2E1 via demethylation and oxidation. Medications that inhibit these may result in an increase in concentrations.

Cost Comparison

	Estimated Acquisition Cost (EAC)	State Maximum Allowable Cost (SMAC)	Recommended Daily Dose	Monthly Cost (30 day supply)
Lunesta® 3 mg	$3.26 per tablet	N/A	3 mg	$ 97.80
Ambien® 10 mg	$3.11 per tablet	N/A	10 mg	$ 93.30
Sonata® 10 mg	$2.79 per capsule	N/A	10 mg	$ 83.70
temazepam 30 mg	$0.78 per capsule	$0.13	30 mg	$ 3.90

Comparison on Current Non-Benzodiazepine Products

	FY 04		FY 03		
Product	**# of Claims**	**Total Cost**	**# of Claims**	**Total Cost**	**% Change**
Sonata® 5mg	258	$16,105.17	422	$25,388.49	36.6 ↓
Sonata® 10mg	1,049	$91,709.27	1,170	$84,308.30	8.8 ↑
Ambien® 5mg	7,898	$505,938.95	7,766	$446,349.03	13.4 ↑
Ambien® 10mg	14,979	$1,236,749.78	11,659	$857,276.81	44.3 ↑

Recommendations

The college of pharmacy recommends the following changes to the current criteria for this category:

- Include Lunesta® in anxiolytic/hypnotic prior authorization category.

References

1. Lunesta® approved product label. http:/www/sepracor.com. 2004

APPENDIX H

Multiple Sclerosis

Oklahoma Medicaid
January 2005

Introduction

Multiple Sclerosis (MS) affects approximately 400,000 patients in the United States and 2 million worldwide, with an estimated 10,000 new cases diagnosed in the United States annually. Most people experience their first symptoms and are diagnosed between the ages of 15 and 50. MS affects women more than man (approx. 3:1).[1]

Signs and Symptoms[2]

Most common symptoms include: fatigue, weakness, spasticity, balance problems, bladder and bowel problems, numbness, vision loss, tremors and depression.
Not all symptoms affect all MS patients. Symptoms may be persistent or cease from time to time. Depending on location of lesion, MS patients may experience the following signs and symptoms:

Lesion location	Signs/symptoms
Cerebrum and Cerebellum	Balance/speech problems, coordination, tremors
Motor Nerve Tracts	Muscle weakness, spasticity, paralysis, vision/bladder/bowel problems
Sensory Nerve Tracts	Altered sensation, numbness, prickling, burning sensation

Types of MS[3]

Name	Characteristics
Relapsing- Remitting Multiple Sclerosis (RRMS)	Symptom flare-ups followed by recovery; stable between attacks
Secondary-Progressive Multiple Sclerosis (SPMS)	Second phase of RRMS; progressive worsening of symptoms w/ or w/o superimposed relapses; treatment may delay or prevent this phase
Primary-Progressive Multiple Sclerosis (PPMS)	Gradual but steady accumulation of neurological problems from onset
Benign	Few attacks and little or no disability after 20 years
Progressive-Relapsing Multiple Sclerosis (PRMS)	Progressive course from the onset, sometimes combined with occasional acute symptom flare-ups
Malignant or Fulminant Multiple Sclerosis	Rapidly progressive disease course

Diagnosis

No single test is available to identify or rule out MS. Several tests and procedures are needed. These include:

1. Complete medical history
    - Overall view of individual's health, including symptoms and when they began
2. Nervous system functioning
    - Testing of reflexes, balance, coordination, vision and checking for areas of numbness
3. Diagnostic tests:
    - MRI- gives detailed view of brain
    - Evoked potential tests- measures how quickly and accurately a person's nervous system responds to certain stimuli
    - Spinal tap- checks spinal fluid for signs of the disease

Treatment- Disease Modifying Agents (DMA)

Drug	Type	Dose	EAC/month
Betaseron	INF beta-1b	250mcg SC qod	$1,219.50
Avonex	INF beta-1a	30mcg IM q wk	Inj- $1,191.32 Kit- $1,069.24
Rebif	INF beta-1a	22mcg SC 3x/wk 44mcg SC 3x/wk	$1,474.68 $1,474.68
Copaxone	Glatiramer acetate	20mg SC qd	$1,119.93

EAC= Average Estimated Acquisition Cost per month; SC= Subcutaneous; IM= Intra-Muscular; INF- Interferon; qod= every other day

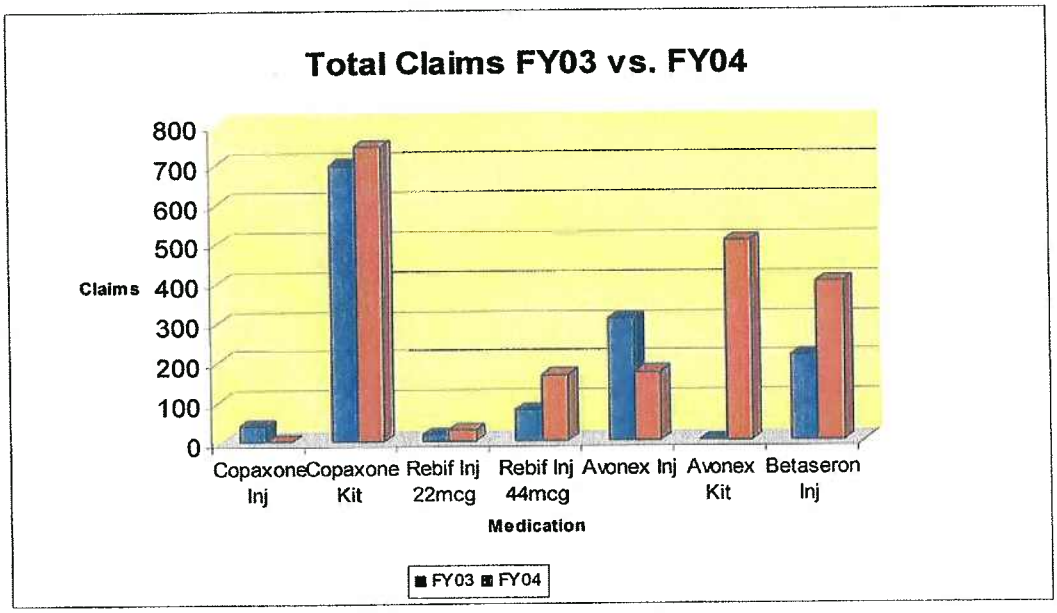
Adverse Effects/Contraindications [4]

Drug	Common AE's	Serious AE's	Contraindications
Betaseron	Injection site rxn, flu-like sx's (fever, chills, myalgia), HA, asthenia	Depression, mental disorders, anaphylaxis, ↑LFT's, palpitations, leukopenia	Hypersensitivity to natural/recombinant INF beta or human albumin products
Avonex	Injection site rxn, flu-like sx's (fever, chills, myalgia), HA	Anaphylaxis, ↑LFT's, anemia, leukopenia, thrombocytopenia, psychiatric disorders, seizures	Hypersensitivity to natural/recombinant INF beta or human albumin products
Rebif	Injection site rxn, flu-like sx's (fever, chills, myalgia), HA	Anaphylaxis, ↑LFT's, anemia, leukopenia, thrombocytopenia, psychiatric disorders, seizures	Hypersensitivity to natural/recombinant INF beta or human albumin products
Copaxone	Anxiety, hypertonia, tremor, arthralgia, asthenia, facial edema, palpitations, transient chest pain, vasodilation, Injection site rxn	HTN, dyspnea, lymphadenopathy, eosinophilia	Hypersensitivity to glatiramer or mannitol

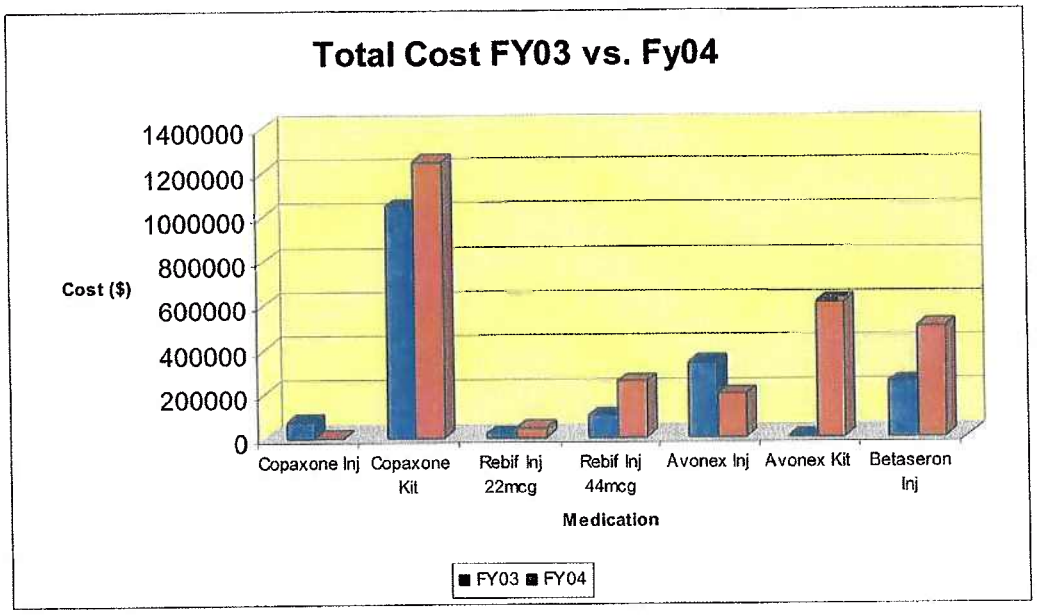
Sx's= symptoms; HA= headaches; rxn= reaction; LFT= Liver function tests;

Trends in Utilization

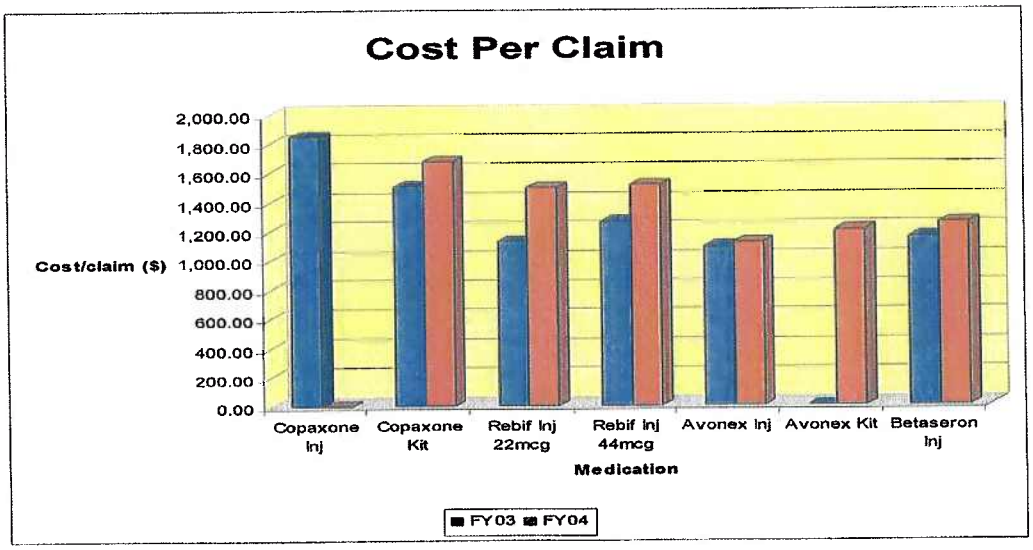
	Fiscal Year 2003	*Fiscal Year 2004*	*Percent Change*
Total Claims	**1349**	**2016**	**33%**
Copaxone Inj 20mg	39	0	-100%
Copaxone Kit 20mg/ml	696	744	6.5%
Rebif Inj 22mg/0.5ml	16	28	43%
Rebif Inj 44mcg/0.5ml	77	166	54%
Avonex Inj 30mcg	308	173	-78%
Avonex Kit	0	506	100%
Betaseron Inj 0.3mg	213	399	47%



	Fiscal Year 2003	*Fiscal Year 2004*	*Percent Change*
Total Cost	**1,813,809.85**	**2,835,827.67**	**36%**
Copaxone Inj 20mg	72,011.97	0	-100%
Copaxone Kit 20mg/ml	1,045,707.42	1,245,470.65	16%
Rebif Inj 22mg/0.5ml	18,092.35	41,911.21	57%
Rebif Inj 44mcg/0.5ml	97,040.17	251,172.82	61%
Avonex Inj 30mcg	336,011.07	193,450.55	-74%
Avonex Kit	0	606,950.96	100%
Betaseron Inj 0.3mg	244,946.87	496,871.48	50%



	Fiscal Year 2003	*Fiscal Year 2004*	*Percent Change*
Cost Per Claim	**7,980.88**	**8246.95**	**3%**
Copaxone Inj 20mg	1,846.46	0	-100%
Copaxone Kit 20mg/ml	1,502.45	1,674.02	10%
Rebif Inj 22mg/0.5ml	1,130.77	1,496.83	24%
Rebif Inj 44mcg/0.5ml	1,260.26	1,513.09	17%
Avonex Inj 30mcg	1,090.95	1,118.21	2%
Avonex Kit	0	1,199.51	100%
Betaseron Inj 0.3mg	1,149.99	1,245.29	8%

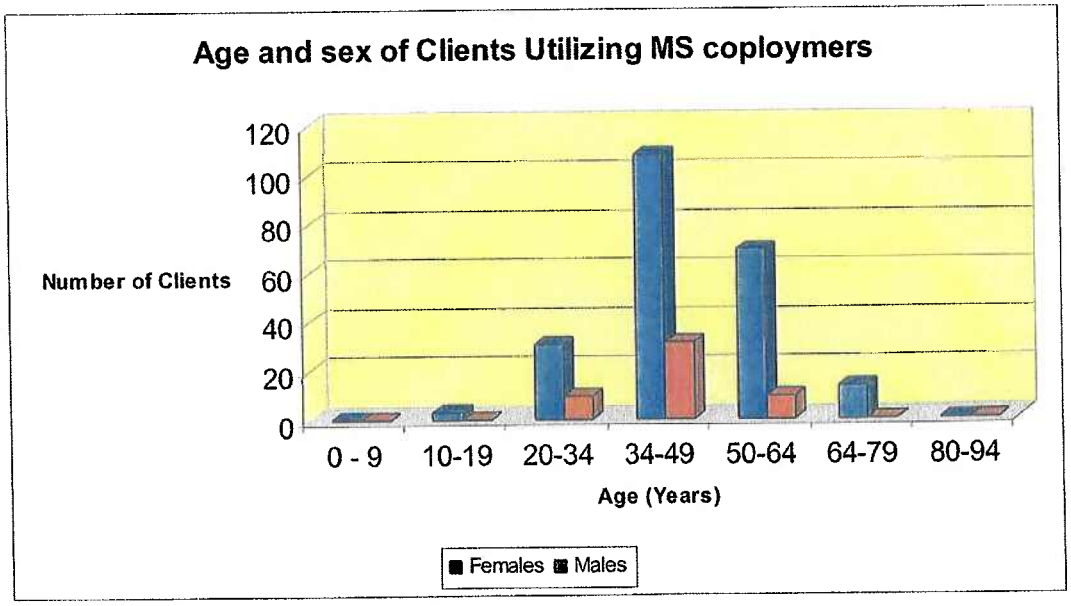


FY03

Drug	Clients	Claims	Cost ($)	Cost/Claim ($)	Claim/Client	Days/Claim	Units/Day
Copaxone Inj 20mg	17	39	72,011.97	1,846.46	3	40	0.56
Copaxone Kit 20mg/ml	98	696	1,045,707.42	1,502.45	7	30	0.32
Rebif Inj 22mg/0.5ml	11	16	18,092.35	1,130.77	2	29	0.22
Rebif Inj 44mcg/0.5ml	13	77	97,040.17	1,260.26	6	30	0.24
Avonex Inj 30mcg	62	308	336,011.07	1,090.95	5	30	0.19
Avonex Kit	-	-	-	-	-	-	-
Betaseron Inj 0.3mg	39	213	244,946.87	1,149.99	6	29	0.56

FY04

Drug	Clients	Claims	Cost ($)	Cost/Claim ($)	Claim/Client	Days/Claim	Units/Day
Copaxone Inj 20mg	-	-	-	-	-	-	-
Copaxone Kit 20mg/ml	113	744	1,245,470.65	1,674.02	7	31	0.30
Rebif Inj 22mg/0.5ml	16	28	41,911.21	1,496.83	2	32	0.29
Rebif Inj 44mcg/0.5ml	25	166	251,172.82	1,513.09	7	29	0.28
Avonex Inj 30mcg	59	173	193,450.55	1,118.21	3	28	0.17
Avonex Kit	77	506	606,950.96	1,199.51	7	29	0.15
Betaseron Inj 0.3mg	53	399	496,871.48	1,245.29	8	29	0.54



Current Treatment Strategies in MS[5]:

Clinical Subform	Therapy
Acute relapse	Pulsed high-dose glucocorticosteroids
Clinically isolated syndrome with high risk of developing clinically definite MS	INF beta
RRMS	First line: INF beta, Copaxone Second line: Mitoxantrone, IVIG, Azathioprine Severe relapses and progression: Mitoxantrone
SPMS	With Relapses: Mitoxantrone, INF beta Progressive: Mitoxantrone Second line: Cyclophosphamide
PPMS	No established therapy
PRMS	Mitoxantrone

- 13 head-to-head, open label studies have compared the IFN-beta products. Results are conflicting, with most suggesting equivalent clinical effects and some showing small differences[6]
- Recently, the FDA approved Tysabri® (Natalizumab) for RRMS

Recommendations:
Based in the information presented and the treatment guidelines by the American Academy of Neurology, the college of pharmacy recommends continued monitoring at this time.

Reference:

[1,3] Multiple Sclerosis Association of America. Available on the internet at: http://www.msaa.com/reading.html

[2] Multiple Sclerosis Foundation: Available on the internet at: http://msfocus.org/info/info_symptoms.html

[4] Micromedex Healthcare Series. Available on the internet at: http://micromedex.ouhsc.edu/

[5] Rizvi SA, Aguis MA. Current approved options for treating patients with multiple sclerosis: Neurology 2004;63; No.6.

[6] Stuart WH, Cohan A, Richet JR, Achiron A. Selecting a disease-modifying agent as platform therapy in the long-term management of multiple sclerosis: Neurology 2004;63; No 11.

APPENDIX I

Prior Authorization Annual Review - Fiscal Year 2004

ADHD/Narcolepsy Drugs

Oklahoma Medicaid
January 2005

Product Based Prior Authorization

With respect to the ADHD/narcolepsy medications, there are two tiers of medications in the therapeutic category. A trial with a tier-1 ADHD medication or a clinical exception to a tier-1 trial is required before a tier-2 ADHD medication can be approved.

Medication	Age Groups	PA Requirements
Ritalin, Ritalin SR, Dexedrine, Dexedrine Spansule, Adderall	Children up to 21 years old	No PA required
	Adults	PA required – Diagnosis of ADHD or narcolepsy.
Ritalin LA, Concerta, Metadate CD, Focalin, Adderall XR, Strattera	Children and Adults	PA Required – Requires trial with Ritalin, Dexedrine or Adderall. Diagnosis of ADHD or narcolepsy.
Desoxyn and Cylert	Children and Adults	PA Required – Requires trial with Ritalin and Dexedrine. Diagnosis of ADHD or narcolepsy.

Fiscal Year '05 Change

When a pharmacy runs a claim for a tier-2 stimulant for a client age 20 or under, the computer system has been programmed to detect tier-1 trials in Medicaid claims in the previous 12 months. If a tier-1 trial is found, the computer allows the tier-2 stimulant claim to pay without requiring a prior authorization petition. Strattera continues to require PA for all ages as a means to monitor for concurrent use of stimulants and Strattera. In order to prevent the computer from automatically allowing claims for high dose tier-2 stimulants, quantity limits have been applied which trigger a PA requirement if the daily dose on the claim exceeds the FDA approved maximum.

Utilization – Fiscal Year 2004

For the period of July 2003 through June 2004, a total of 16,816 clients received ADHD medications through the Oklahoma Medicaid fee-for-service program.

Tier	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Clients	$/Day	$/ Client
Tier 1	40,346	2,508,790	1,230,505	2.12	$1,710,601.21	9,972	$1.45	$171.54
Tier 2	53,747	1,957,955	1,642,855	1.21	$5,335,692.96	10,541	$3.30	$506.18
Total	**94,093**	**4,466,745**	**2,873,360**	**1.60**	**$7,046,294.17**	**16,816***	**$2.51**	**$419.02**

*Total unduplicated clients for FY04

Total Cost FY '04	**$7,046,294.17**
Total Cost FY '03	*$4,102,884.76*
Total Claims FY '04	**94,093**
Total Claims FY '03	*61,774*
Total Clients FY '04	**16,816**
Total Clients FY '03	*11,575*
Per Diem FY '04	**$2.51**
Per Diem FY '03	*$2.25*

Total petitions submitted for this category during FY 2004:

Approved..... 16,900
Denied..... 5,643
Incomplete 2,366

Claims were reviewed to determine the age/gender of the clients.

Age	Female	Male	Totals
0 to 9	1,917	5,332	7,249
10 to 19	2,374	6,612	8,986
20 to 34	145	99	244
35 to 49	126	61	187
50 to 64	55	28	83
65 to 79	26	10	36
80 to 94	22	6	28
95 and Over	3	0	3
Totals	**4,668**	**12,148**	**16,816**

News

Modafinil for ADHD:
Modafinil, currently available as Provigil®, is available in 100 and 200 mg strength tablets. Provigil® is expected to go off patent in the near future. The manufacturer of Provigil® is developing a new proprietary form of modafinil called Attenace®, which will be available in 85, 170, 255, 340, and 425 mg strengths. A supplemental new drug application for Attenace® was filed with the FDA on 12/21/04. Approval is being sought for the indication of the treatment of attention deficit/hyperactivity disorder (ADHD) in children and adolescents between the ages of six and 17. The company is targeting a launch of Attenace® by early 2006. In the meantime, the Phase 3 study data are expected to be presented at major medical meetings in 2005. The company hopes to capture a substantial portion of the ADHD marketplace with Attenace®.

New Concerta® Dosing:
Concerta® recently received FDA approval for a new maximum dose of 72 mg once daily. The maximum dose had been 54 mg once daily. The manufacturer has not made the higher dosage strength available, so the drug is still available in 18, 27, 36, & 54 mg tablets. This means that clients will need at least two tablets to achieve the new maximum dose. The college of pharmacy PA unit is now approving requests for 72 mg once daily if the client meets the other criteria, and can approve up to 108 mg once daily if the prescriber provides the extra information requested for high dose petitions.

New Warning about Strattera®:
On 12/17/04, the manufacturer of Strattera® announced that it added a new bolded warning to the product label for Strattera® (atomoxetine). The warning concerns the potential for severe liver injury following reports of liver damage in two patients (a teenager and an adult) who had been treated with Strattera® for several months. The medication should be discontinued in patients who develop jaundice or laboratory evidence of liver injury. The company is in the process of notifying physicians, other health care providers and consumer advocacy and professionally focused associations about this label change. The company will be sending out a Dear Health Professional letter and will update the patient package insert with information about the signs and symptoms of liver problems.

Recommendations

The college of pharmacy recommends no change in the coverage policies for this category at this time.

APPENDIX J

Drug Abuse Warning Network

The DAWN Report

APRIL 2004

Benzodiazepines in Drug Abuse-Related Emergency Department Visits: 1995-2002

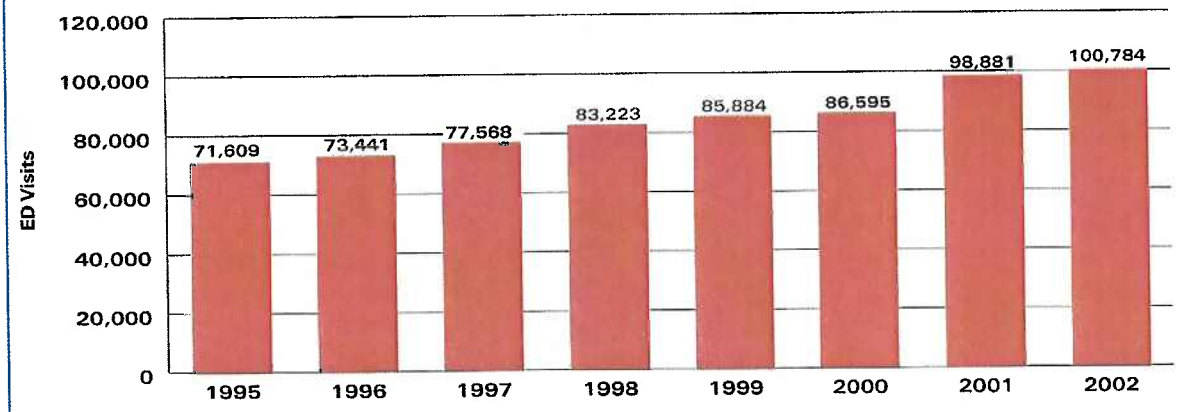
In Brief

Benzodiazepines are psychotherapeutic sedatives used to treat anxiety, insomnia, and seizures. Examples of some common brands include Valium®, Xanax®, Librium®, and Ativan®.

- In 2002, over 100,000 drug abuse-related emergency department (ED) visits involved benzodiazepines.
- Drug abuse-related ED visits involving benzodiazepines increased 41 percent from 1995 to 2002.
- Alprazolam and clonazepam were the benzodiazepines most frequently reported in drug abuse-related ED visits in 2002. However, a third of total benzodiazepine mentions were reported only as "benzodiazepine," with no specific drug name.
- Most benzodiazepine-related ED visits (78%) involved more than one drug.
- Alcohol was the substance most frequently reported with benzodiazepines in drug abuse-related ED visits.

FIGURE 1

Trends in benzodiazepine-involved ED visits: 1995-2002



Source: Office of Applied Studies, SAMHSA, Drug Abuse Warning Network, 2002 (3/2003 update).

The DAWN Report is published periodically by the Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA). This issue was written by Elizabeth H. Crane, Ph.D. (OAS/SAMHSA). Nita Lemanski (Westat) also contributed to this report.

Background

Currently, the abuse of benzodiazepines attracts less attention than the abuse of other prescription drugs, such as opiate pain medications. However, benzodiazepines were involved in over 100,000 drug abuse-related ED visits in 2002 and were the most frequently mentioned type of psychotherapeutic drug.

Trends, 1995-2002

From 1995 to 2002, drug abuse-related ED visits involving benzodiazepines increased 41 percent, from 71,609 to 100,784 (Figure 1). In contrast, total drug abuse-related ED visits increased 31 percent.

Total benzodiazepine-related ED visits were stable from 2001 to 2002, but trends varied for individual drugs (Figure 2). Among the benzodiazepines that were specified by name, increases in ED visits were observed for alprazolam (62%) and clonazepam (33%) from 1995 to 2002. In 2002, 33 percent of benzodiazepine mentions were not specified by name *(not otherwise specified, or NOS)*.[1] This category of unnamed benzodiazepines increased 199 percent during that period, but it is not possible to know which drugs were responsible for the increase. Visits including diazepam, lorazepam, and temazepam were stable from 1995 to 2002, while visits involving chlordiazepoxide decreased by 74 percent. Visits including any of these drugs were stable from 2001 to 2002.[2]

In 2002, alprazolam was involved in a quarter of the benzodiazepine-related ED visits (27,659 visits). Clonazepam was involved in 16 percent of benzodiazepine-related ED visits (17,042 visits).

Benzodiazepines and polydrug abuse

Over three-quarters (78%) of benzodiazepine-related visits involved 2 or more drugs (Figure 3). On average, 2 drugs were reported for each benzodiazepine-related ED visit.

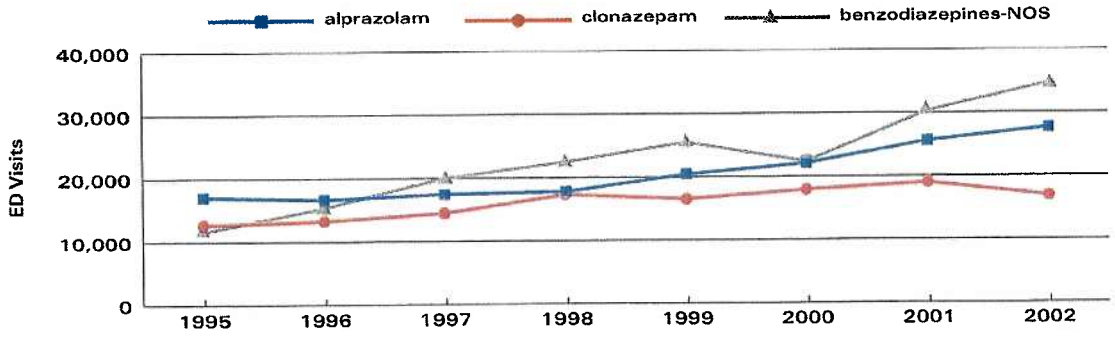
Benzodiazepines were most frequently combined with alcohol, illicit drugs, and opiate pain medications in drug abuse-related ED visits (Table 1). Alcohol was involved in more than twice as many benzodiazepine-related visits as marijuana, the second most frequently mentioned drug. Furthermore, when the specific drug combinations are ranked by frequency, alcohol appears in 8 of the top 15 combinations involving benzodiazepines.

When multiple drugs are involved in an ED visit, it is not always possible to determine which drug caused the visit, or if the visit resulted from the interaction between the drugs. It is possible that, in some of these ED visits, use of benzodiazepines was incidental to the visits.

Nonetheless, these findings highlight the problem of polydrug abuse involving benzodiazepines and suggest that prevention efforts will need to address the practice of combining prescription drugs with illicit drugs and alcohol.

FIGURE 2

Benzodiazepines in drug abuse-related ED visits: Increases, 1995-2002



Source: Office of Applied Studies, SAMHSA, Drug Abuse Warning Network, 2002 (3/2003 update)

[1] This can occur because some screening tests do not differentiate between different types of benzodiazepines.
[2] Estimates for benzodiazepines not included in this report can be found in Table 2.6.0 in *Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995-2002*, available at: http://DAWNinfo.samhsa.gov/.

TABLE 1

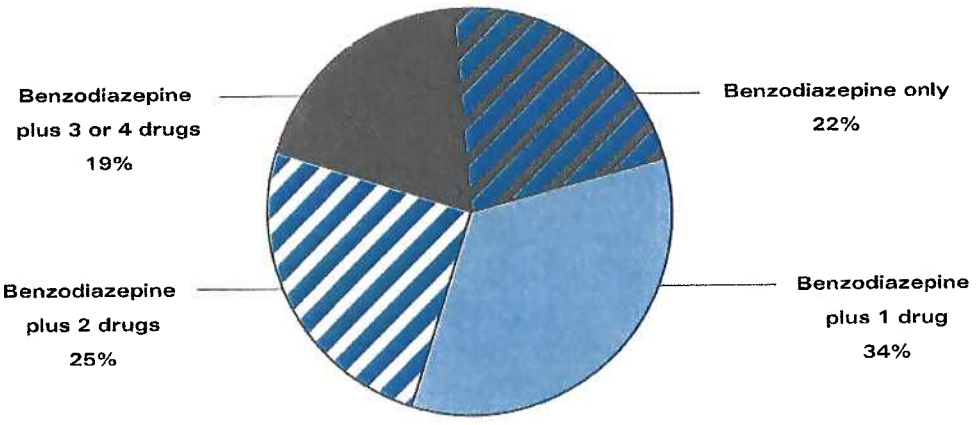
Drugs most frequently combined with benzodiazepines: 2002

Rank	Drug	Type of drug	Visits
1	alcohol		33,130
2	marijuana	illicit	14,795
3	cocaine	illicit	13,961
4	narcotic analgesics-NOS	narcotic analgesic	10,525
5	acetaminophen-hydrocodone	narcotic analgesic	5,653
6	heroin	illicit	4,040
7	amphetamine	illicit/stimulant	3,092
8	methadone	narcotic analgesic	3,013
9	oxycodone	narcotic analgesic	2,807
10	carisoprodol	muscle relaxant	2,643
11	barbiturates-NOS	sedative-hypnotic	2,579
12	zolpidem	sedative-hypnotic	2,425
13	paroxetine	antidepressant	1,902
14	acetaminophen-oxycodone	narcotic analgesic	1 743
15	acetaminophen	analgesic	1,649

Source: Office of Applied Studies, SAMHSA, Drug Abuse Warning Network, 2002 (3/2003 update).

FIGURE 3

Frequency of polydrug use in benzodiazepine-involved ED visits: 2002



Source: Office of Applied Studies, SAMHSA, Drug Abuse Warning Network, 2002 (3/2003 update).

About DAWN

The **Drug Abuse Warning Network (DAWN)** is a national public health surveillance system that collects data on drug abuse-related visits to emergency departments (EDs) and drug abuse-related deaths reviewed by medical examiners and coroners. Data on ED visits are collected from a national probability sample of non-Federal, short-stay hospitals, with oversampling in 21 major metropolitan areas. Data from the sample are used to generate estimates for the coterminous U.S. and the 21 metropolitan areas.

ED visits are reportable to DAWN if a patient between the ages of 6 and 97 was treated for a condition associated with intentional drug abuse, including recreational use, dependence, or a suicide attempt. Visits involving chronic health conditions resulting from drug abuse are reportable. Abuse of prescription and over-the-counter medications is reportable. Adverse reactions associated with appropriate use of these drugs and accidental ingestion or inhalation of any drug are not reportable.

In DAWN, drugs are described by their generic names. An index linking brand (trade) names with generic drug names is available at http://DAWNinfo.samhsa.gov/.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

News Release
FOR IMMEDIATE RELEASE
December 15, 2004

Turn In Pharmaceutical Pill Pushers Confidentially Call 1-877-RxAbuse
DEA Unveils International Toll-Free Hotline to Report Illegal Prescription Drug Sales and Rogue Pharmacies Operating on the Internet

DEA has launched a toll-free international hotline to report the illegal sale and abuse of pharmaceutical drugs. People now will be able to provide anonymous telephone tips about the diversion of prescription drugs into the illegal market by individuals and suspicious Internet pharmacies. In addition, such information can be reported online through the DEA Webpage.

According to DEA Administrator Karen P. Tandy, "For the first time -- with one simple call -- people in the United States and Mexico have an anonymous, safe, and free way to bring information about suspected illegal pharmaceutical distribution to DEA. This information will greatly assist us in bringing drug dealers to justice and preventing the tragedies that come from prescription drug abuse."

Abuse of certain prescription drugs -- controlled substances such as pain killers and performance enhancing steroids -- has become an increasingly widespread problem in the United States, leading to dangerous abuse, addiction and sometimes fatalities. The 2003 National Survey on Drug Use and Health reports 6.3 million persons currently use prescription medications non-medically.

"DEA is particularly interested in hearing from families whose loved one has overdosed or died as a result of obtaining pharmaceuticals over the Internet. Tips including the Web addresses will help us put these pill pushers out of business," Tandy stated. Anonymous reports will be taken at 1-877-RxAbuse or can be made online at www.dea.gov by clicking on a link and filling out an electronic form

According to data collected by the Drug Abuse Warning Network (DAWN), since 1995 the number of drug abuse-related emergency room visits involving pain relievers such as Vicodin, Percocet, OxyContin and Darvon, increased 153 per cent from (from 42,857 to 108,320). One out of every ten high school seniors now reports abusing powerful prescription pain killers.

Preliminary data from the Partnership for a Drug-Free America's Attitude Tracking Study suggests that many adolescents do not consider pharmaceutical drug abuse risky. Unless attitudes change, more teens may be willing to experiment with these types of drugs in the future.

DEA's prescription drug abuse hotline is up and running. We expect callers will provide leads that will help root out offenders and shut down their illegal operations. But our work doesn't stop here. We are also meeting with citizen groups, health professionals, businesses, civic leaders, and educators across the country to let the American public know that prescription drugs are dangerous when misused and potentially fatal. This is a critical message for America's youth,"the Administrator added.

In March of this year, DEA, the Office of National Drug Control Policy, the Food and Drug Administration, and the Surgeon General announced a coordinated, comprehensive plan to address the problem of prescription drug abuse as part of the President's 2004 National Drug Control Strategy. This prescription drug abuse hotline is one piece of the strategy.

In a related piece of the President's National Strategy, DEA also is pursuing illegal Internet drug

operations. A flashing notice on the DEA Webpage (www.dea.gov) already enables people to report suspicious Internet pharmacies online. With a click of the mouse, people can pull up a simple form that allows them to get this information to DEA in a timely fashion. Since the web notice went up in June, we have received 810 tips.

Callers will be able to make confidential reports by dialing toll free 1-877-RxAbuse (1-877-792-2873) around the clock, 365 days per year. The hotline will be staffed by bilingual operators housed at DEA's El Paso Intelligence Center (EPIC). This is a toll free call from Mexico as well.

During normal business hours the caller will be connected directly to someone at the responsible DEA Domestic Field Office. After-hours tips will be forwarded by an internal, secure E-mail system, for further investigation and follow-up, by DEA Agents and Investigators.

U.S. Food and Drug Administration

FDA Talk Paper

T04-61
December 23, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-F

FDA Issues Public Health Advisory Recommending Limited Use of Cox-2 Inhibitors

Agency Requires Evaluation of Prevention Studies Involving Cox-2 Selective Agents

The Food and Drug Administration (FDA) today issued a Public Health Advisory summarizing the agency's recent recommendations concerning the use of non-steroidal anti-inflammatory drug products (NSAIDs), including those known as COX-2 selective agents. The public health advisory is an interim measure, pending further review of data that continue to be collected.

In addition, FDA today announced that it is requiring evaluation of all prevention studies that involve the Cox-2 selective agents Celebrex (celecoxib) and Bextra (valdecoxib) to ensure that adequate precautions are implemented in the studies and that local Institutional Review Boards reevaluate them in light of the new evidence that these drugs may increase the risk of heart attack and stroke. A prevention trial is one in which healthy people are given medicine to prevent a disease or condition (such as colon polyps or Alzheimer's disease).

FDA is issuing an advisory because of recently released data from controlled clinical trials showing that the COX-2 selective agents (Vioxx, Celebrex, and Bextra) may be associated with an increased risk of serious cardiovascular events (heart attack and stroke) especially when they are used for long periods of time or in very high risk settings (immediately after heart surgery).

Also, as FDA announced earlier this week, preliminary results from a long-term clinical trial (up to three years) suggest that long-term use of a non-selective NSAID, naproxen (sold as Aleve, Naprosyn and other trade name and generic products), may be associated with an increased cardiovascular (CV) risk compared to placebo.

Although the results of these studies are preliminary and conflict with other data from studies of the same drugs, FDA is making the following interim recommendations:

- Physicians prescribing Celebrex (celecoxib) or Bextra (valdecoxib), should consider this emerging information when weighing the benefits against risks for individual patients. Patients who are at a high risk of gastrointestinal (GI) bleeding, have a history of intolerance to non-selective NSAIDs, or are not doing well on non-selective NSAIDs may be appropriate candidates for Cox-2 selective agents.
- Individual patient risk for cardiovascular events and other risks commonly associated with NSAIDs should be taken into account for each prescribing situation.
- Consumers are advised that all over-the-counter (OTC) pain medications, including NSAIDs, should be used in strict accordance with the label directions. If use of an (OTC) NSAID is needed for longer than ten days, a physician should be consulted.

Non-selective NSAIDs are widely used in both over-the-counter (OTC) and prescription

settings. As prescription drugs, many are approved for short-term use in the treatment of pain and primary dysmenorrhea (menstrual discomfort), and for longer-term use to treat the signs and symptoms of osteoarthritis and rheumatoid arthritis. FDA has previously posted extensive NSAID medication information at http://www.fda.gov/cder/drug/analgesics/default.htm.

FDA is collecting and will be analyzing all available information from the most recent studies of Vioxx, Celebrex, Bextra, and naproxen, and other data for COX-2 selective and nonselective NSAID products to determine whether additional regulatory action is needed. An advisory committee meeting is planned for February 2005, which will provide for a full public discussion of these issues.

FDA urges health care providers and patients to report adverse event information to FDA via the MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by the Internet at http://www.fda.gov/medwatch/index.html.

The Public Health Advisory is available online at www.fda.gov/cder/drug/advisory/nsaids.htm.

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FDA Talk Paper

T04-60
December 17, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-F

New Warning for Strattera

The Food and Drug Administration (FDA) is advising health care professionals about a new warning for Strattera, a drug approved for attention deficit hyperactivity disorder (ADHD) in adults and children. The labeling is being updated with a bolded warning about the potential for severe liver injury following two reports (a teenager and an adult) in patients who had been treated with Strattera for several months, both of whom recovered.

The labeling warns that severe liver injury may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients. The labeling also notes that the number of actual cases of severe liver injury is unknown because of under-reporting of post-marketing adverse events.

The bolded warning indicates that the medication should be discontinued in patients who developed jaundice (yellowing of the skin or whites of the eyes) or laboratory evidence of liver injury.

Strattera has been on the market since 2002 and has been used in more than 2 million patients. In clinical trials of 6000 patients, no signal for liver problems (hepatotoxicity) had emerged.

FDA has asked the manufacturer to add a bolded warning about severe liver injury to the labeling. Eli Lilly has agreed to alert health care professionals about the new information in a Dear Health Professional letter. The company will also update the patient package insert with information about the signs and symptoms of liver problems, which include:

- Pruritus (Itchy skin)
- Jaundice
- Dark urine
- Upper right-sided abdominal tenderness
- Or unexplained "flu-like" symptoms

Health care professionals are encouraged to report any unexpected adverse events associated with Strattera directly to Eli Lilly, Indianapolis, Ind., at 1800-LillyRx or to the FDA MedWatch program at 1800-FDA-1088. The MedWatch form is available online at http://www.fda.gov/medwatch/safety/3500.pdf for download by mail (or fax, 1800-FDA-0178) to MedWatch, HFD-410, FDA, 5600 Fishers Lane, Rockville, Md. 20857.

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FDA News

FOR IMMEDIATE RELEASE
P04-111
December 23, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-F

FDA Clears First of Kind Genetic Lab Test

The Food and Drug Administration (FDA) today cleared for marketing the first laboratory test system that will allow physicians to consider unique genetic information from patients in selecting medications and doses of medications for a wide variety of common conditions such as cardiac disease, psychiatric disease, and cancer.

"Physicians can use the genetic information from this test to prevent harmful drug interactions and to assure drugs are used optimally, which in some cases will enable patients to avoid less effective or potentially harmful treatment choices," said Dr. Lester M. Crawford, Acting FDA Commissioner.

The new test is the AmpliChip Cytochrome P450 Genotyping Test made by Roche Molecular Systems, Inc., of Pleasanton, Calif. It was cleared for use with the Affymetrix GeneChip Microarray Instrumentation System, manufactured by Affymetrix, Inc., of Santa Clara, Calif.

The new test is the first DNA microarray test to be cleared by the FDA and its clearance paves the way for similar microarray-based diagnostic tests to be developed in the future. A microarray is similar to a computer microchip, but instead of tiny circuits, the chip contains millions of tiny DNA molecules. The test is performed using DNA that is extracted from a patient's blood. A person's DNA sequence is determined based on the sequence of the probe molecule to which the DNA is most similar.

The new test analyzes one of the genes from a family of genes called cytochrome P450 genes, which are active in the liver to break down certain drugs and other compounds. Variations in this gene can cause a patient to metabolize certain drugs more quickly or more slowly than average, or, in some cases, not at all. The specific enzyme from this family that is analyzed by this test, called cytochrome P4502D6, plays an important role in the body's ability to metabolize some commonly prescribed drugs including antidepressants, anti-psychotics, beta-blockers, and some chemotherapy drugs.

The test is not intended to be a stand-alone tool to determine optimum drug dosage, but should be used along with clinical evaluation and other tools to determine the best treatment options for patients.

FDA cleared the test and the scanner based on results of a study conducted by the manufacturers of hundreds of DNA samples as well as on a broad range of supporting peer-reviewed literature.

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