THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Ron Graham, D.Ph.

SUBJECT: **Packet Contents for Board Meeting – March 9, 2004**

DATE: March 4, 2004

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

Enclosed are the following items related to the March 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.**

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

Action Item – Vote on Prior Authorization of Forteo™ - **See Appendix C.**

Annual Review of Non-Sedating Antihistamines (NSA) Utilization – **See Appendix D.**

Annual Review of Plavix™ Utilization - **See Appendix E.**

Annual Review of Anxiolytics / Hypnotics Utilization – **See Appendix F.**

Review and Discuss Synagis™ Utilization – **See Appendix G.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – March 9, 2004 @ 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. February 10, 2004 DUR Minutes

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

4. **Update on DUR/MCAU Program - See Appendix B.**
   A. Medication Coverage Activity Audit for February 2004
   B. Help Desk Activity Audit for February 2004

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

5. **Action Item – Vote on Prior Authorization of Forteo™ - See Appendix C.**
   A. COP Recommendations

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

6. **Annual Review of Non-Sedating Antihistamines (NSA) Utilization – See Appendix D.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

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

7. **Annual Review of Plavix™ Utilization – See Appendix E.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

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

8. **Annual Review of Anxiolytics / Hypnotics Utilization – See Appendix F.**
   A. Oklahoma Medicaid utilization
   B. COP Recommendations

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

9. **Review and Discuss Synagis™ Utilization – See Appendix G.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

10. **FDA and DEA Updates – See Appendix H.**

11. **Future Business**
   A. Antiviral Utilization Review
   B. Hepatitis C Agents Review
   C. Anti-asthmatics Review
   D. Tamiflu Review
   E. Epogen / Procrit Review
   F. Annual Review of Antihypertensives

12. **Adjournment**

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of FEBRUARY 10, 2004

BOARD MEMBERS:	PRESENT	ABSENT
Rick G. Crenshaw, D.O.	X	
Dorothy Gourley, D.Ph.	X	
Cathy Hollen, D.Ph.	X	
Thomas Kuhls, M.D.	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	
Greg Tarasoff, M.D.	X	
Thomas Whitsett, M.D., Chair	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph./Clinical Pharmacist	X	
Jack Coffey, Assistant Dean, College of Pharmacy		X
Karen Egesdal, D.Ph./Clinical Pharmacist/OHCA Liaison	X	
Kelly Flannigan, D.Ph./Clinical Pharmacist	X	
Shellie Gorman, Pharm.D./Clinical Pharmacist	X	
Ronald Graham, D.Ph., Manager, Operations/DUR	X	
Elgene Jacobs, Ph.D.; Manager, Research		X
Chris Kim Le, Pharm.D.; Clinical Pharmacist	X	
Ann McIlvain, Pharm.D.; Clinical Pharmacist	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Douglas Voth, MD./Dean , College of Pharmacy		X
Visiting Pharmacy Students: Chris Brown, Amanda Croley, Tammy Grove, Chris Nededog, Elija Pham, Jodi Sparkman, Gretchen Imel	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Kristall Bright; Pharmacy Financial Analyst	X	
Alex Easton, M.B.A.; Pharmacy Operations Manager	X	
Mike Fogarty, C.E.O	X	
Lynn Mitchell, M.D., M.P.H, Medical Director	X	
Nancy Nesser, D.Ph., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.		X
Lynn Rambo-Jones, J.D.	X	
Rodney Ramsey; Pharmacy Claims Specialist	X	

OTHERS PRESENT:

Charlene Kaiser, Wyeth	Tom Hurt, Wyeth	Aliza Tomlinson, Janssen
JimTincher, Sepracor	Jill Miller, TAP	Jim Goddard, Shire
Pat Evans, BMS	Ron Schnare, Abbott	Kay Kaut, Amylin
Woodie Zachry, Lilly	Jack Jones, Lilly	Eric Renteria, Schering
Tara Linville, Sepracor	Leo Hauser, Pfizer	Scott Johnson, Pfizer
Vic Stephens, Shire	Liz Daily, BMS	Holly Jacques, Merck
Vickie Marton, BMS	David Poskey, Abbott	Jore Nassar, BMS
Mark DeClerk, Lilly		

PRESENT FOR PUBLIC COMMENT:

Jeff Tallent, NAMI

Woodie Zachry, Ph.D.; Lilly

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

1A: Roll Call

Dr. Whitsett called the meeting to order. 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

Woodie Zachry, general comments: *My name's Dr. Woodie Zachry. I'm outcomes liaison with Eli Lilly & Company, that's my title, but I really a field-based representative of US Medical. I help people with requests for information and research. What I wanted to talk about, really, I specialize in mental illness and there are four points that were brought up about atypicals that I just wanted to address and then really offer, it's real easy to get a hold of me, I can provide any of this evidence you'd like, and that's really the mainstay of my job, is to provide this evidence to people making decisions, difficult decisions. The first is that you have to PA to be able to understand the use of these products in the population. You talked about there was differential diagnoses and a lot of off-label use of these products and there are things that you really have to delve into the data to really find out the use patterns. One of the things that we had put forward was an appropriate use program and that's really what this is geared toward, is rather than trying to restrict to find out really what's going on within that drug use and instead of taking a tack of potentially harming a vulnerable population, go in and surgically try to figure out what's going on and intervene educationally and with follow-up to get people back on to evidence based practices. So there is a way to try and do it, there is a way to measure the impact that goes into those interventions as well that would be worthwhile. I do have information about using that program in other states, can help you with that. The second, no better than atypicals. There is a meta analysis, that's available that measures effect sizes of looking at the typical agents versus atypical agents. Meta analysis is a very difficult, esoteric tool in statistics, it's very, and it's very hard to implement, an idea, just general. What we're doing is taking a lot of studies of various methodologies and various populations with different outcomes at different lengths of time and trying to aggregate them into one coherent result. Trying to take advantage of all the incise in these trials and put them into one coherent result, but as a result, you have to do a lot of transformations to make them, I guess sing the same tune. There was a meta analysis that did come out that questioned the effect side of typicals versus atypicals; however, a second meta analysis was done on the very same data. And it came out with markedly different conclusions. And it speaks to the difficulty of really doing meta analysis, I would love to provide that, if you'd like to have it. And also we have to think about, when a new article comes on the market, and it comes into the scientific literature and it comes into our awareness, we have to look at it in the context of the body of literature in this respect and I can help with that as well. The body of literature truly does demonstrate that negative effects and dyskinetic movement disorders are lower in the atypical class and that's where their primary value is, is negative symptoms. Symptoms of disconnecting from relationships. Finally no difference, if you look, second to the last, sorry I want to make this quick. No difference between the agents. The literature on atypicals is not very old, not very mature. We haven't had very many head-to-head trials. We have had head-to-head trials, however they're in the process, embargoed for publication and so forth. There are again some information in the public domain of head-to-head trials that I can help you with as well. Most of it is in poster form and either is in press or is provided as well. There is a great review by Hudson that looks at the pharmacoeconomic value of these products versus typicals that I can point out as well. There is a good review by Les Sittrom in the Harvard Review of Psychiatry that summarizes information nicely in looking at between typicals and typicals versus atypicals and between atypicals as well. There are, and you have to look at the evidence we have right now. We have very short term evidence. Long term evidence is coming up in the market, coming into the literature as this area of literature matures and we're able to find this information. Looking at short term outcomes on PAN scores may be insufficient based on what we treat our patient for in the real world. We don't treat to a PAN score as much as we treat the functionality. And it's very difficult to capture that in clinical trials, but we can capture it in naturalistic trials and I have a wealth of information for you on that as well. Finally, cost difference. You talked about the Riscotti article. I have copies of it here, one of the few articles I have with me at this point. Sorry I didn't bring the rest of it. But if you'd like a copy I can get it to you. I'd love to be able to talk to you about it. Because it's very easy to take a misleading message from something unless you put it in context. In looking at the Riscotti article, really what it talks about is that a very concerted appropriate methodology that there is cost shift in this population. They're used for different uses, but when we can finally narrow it down to similar uses and similar refractoriness or difficulty of the disease state, severity of the disease state, you can truly start to see the true cost implications of using one agent or another. And it is head-to-head data so I can provide that as well. Speaking to what was brought up, the case mix issue as well, we know in naturalistic research, before I came on with Lilly, I was professor at the University of Arizona. My specialty was doing naturalistic research and cost implication research. We know there are things that occur in this population that are very difficult to account for, such as dose tolerability issues that may change prescribing patterns and there are things that we have to do to try and take care of the data to get a true look at what the data's trying to tell us. I'd love to be able to put in context for you.*

Dr. Kuhls: *So you believe that there is differences in effectiveness of atypicals?*

Dr. Zachry: *Yes.*

Dr. Kuhls: *And certain patients, one atypical might be better than the others?*

Dr. Zachry: *Yes.*

Dr. Kuhls: *Which patients specifically as a clinician would you not start on Zyprexa? And you would pick a different atypical?*
Dr. Zachry: *This is a, OK, let me start off with a basis. This is a really a clinician decision based on their past treatment pattern. We have a huge prevalence of schizophrenia and then we have an incidence. When you're starting that new case, we're talking about a new case, there are different tolerability issues among the agents. Let me speak to that. Zyprexa weight gain is an issue. Specifically it is a significant issue in about a fifth of the population that's starting, so you have to look at that issue. Diabetes, the FDA has come out with a ruling that said all the agents might be a class effect and also might be a disease state effect, so that's not the issue.*
Dr. Kuhls: *So maybe what you should say is that maybe what this Board should look at is anybody who's obese we should try to not use Zyprexa?*
Dr. Zachry: *BMI though, there is some disease state recovery weight gain. Higher BMIs are actually associated with less weight gain, starting on Zyprexa.*
Dr. Kuhls: *OK, so you just refuted what you initially said.*
Dr. Zachry: *No, lower BMIs are associated with . . .*
Dr. Kuhls: *So my question is which patient population wouldn't you start on Zyprexa?*
Dr. Zachry: *That's up to the clinician based on . . .*
Dr. Kuhls: *So you're not going to answer that. My second question is . . .*
Dr. Zachry: *It's not that I don't want to answer it, it's a very complex answer . . .*
Dr. Kuhls: *Well, you're telling me there's differences in atypicals between patient populations and you're trying to get us to believe that, and so my answer is, well if there's differences and you can show that, then which patients isn't Zyprexa the best drug? That's what I'm asking.*
Dr. Zachry: *Let me draw you an analogy as to what I'm trying to get across. There are, the literature is not mature enough to put in clinical buckets. Similar to what we had with cancer before, and it's in the stage to some extent. There are agents that are proved within class, but there's a lot of experimentation because it's a difficult disease state to treat, so that trying to cordon off to say we're only going to allow you to use it within this population, you don't allow in a very devastating and vulnerable population, the ability of people to use these drugs where they've had failures before, so that's why I keep coming back to the fact that there are measured differences, the literature might not be mature enough to reflect those differences, but the practitioners see it every day.*
Dr. Kuhls: *So what you're saying is that we can probably get away with starting one drug, but it may not be as effective as another drug and the way to find that out is if you fail the first drug, then you try a second drug. That's what you're basically saying.*
Dr. Zachry: *I would say similar to what we see with TMAP . . . TMAP algorithm. We start off with the clinician being able to under. . . have all these drugs in their armament available for them and based on that patient's history they can choose an agent, but the onus is on them to follow-up that patient and make sure they have adequate outcomes . . . positive outcomes. If they don't it's time to switch the treatment before failure. . . avoid failure.*
Dr. Kuhls: *Well I agree. That sounds good. My second question is, where do you live, what state?*
Dr. Zachry: *Houston, Texas.*
Dr. Kuhls: *OK.*
Dr. Zachry: *Oklahoma is part of my territory.*
Dr Kuhls: *I don't know . . .man . . . that's to talk . . . I'm from, not Oklahoma originally, but you probably for a couple of people here, when they hear Texas, they're not going to believe you as much. So I didn't mean that purposely, but . . . do you like paying Texas taxes?*
Dr. Zachry: *Do I like paying Texas taxes? That's a double edged question. I don't like paying taxes, but I see the utility.*
Dr. Kuhls: *I mean, you live in Texas, so tell me about state income taxes and so on.*
Dr. Zachry: *Texas doesn't have a state income tax.*
Dr. Kuhls: *OK. We have taxes here and we're all taxpayers so can you understand that we're concerned that we want to give the most effective medicine but we want to give the cheapest medicine possible.*
Dr. Zachry: *Absolutely.*
Dr. Kuhls: *Do you agree with that concept?*
Dr. Zachry: *Absolutely. But the pharmacy budget doesn't live in a vacuum. If we try and cut costs in the pharmacy budget we have to understand it does impact psychiatric care and general health. If schizophrenics aren't taking care of their schizophrenia, their diabetes, their congestive heart failure, and so forth is going to suffer as well. So whatever impact we make in the pharmacy budget, we have to worry about how it's going to impact those concentric circles. And there is data from the Kaiser Family . . . Kaiser Health Foundation that's . . . it's industry independent, that's shown the impact of restrictions in vulnerable populations for central medications on these global budgets . . . and seen, for instance in Michigan, and in New Hampshire were summarized that these restrictions of vulnerable populations have actually cost more. If we don't go after the appropriate use type of methodology, and that's what we're trying to do with the CNS Program.*

Dr. Whitsett: *I think we need to curtail this. We've had that conversation numerous times in the past and have not resolved it yet, but appreciate your comments.*
Dr. Zachry: *Thank you for your time.*

Dr. Whitsett recognized Jeff Tallent, public comment for Agenda Item No. 5.

Dr. Whitsett acknowledged Keith Schafer, guest speaker for Agenda Item no. 5.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: January 13, 2004 DUR Minutes

Correction noted to page 3, Agenda Item no. 7 of the minutes of 01-13-04, "Dr. Tarasoff gave some answers to the question", rather than "Dr. Tarasoff asked the question".
Dr. Tarasoff moved to approve minutes; motion seconded by Dr. Meece.
ACTION: MOTION CARRIED.

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

4A: Retrospective DUR Report: October 2003

All drug interactions (female) were selected for retrospective review for October 2003. Pharmacy and physician response was 52% and 55% respectively. Savings related to this DUR run was $119,428. Potential annualized savings total calendar-YTD is $1,401,325. Reports included in agenda packet; presented by Dr. Flannigan.

4B: Medication Coverage Activity Report: January 2004

The January 2004 activity audit noted total number of petitions submitted was 15,688 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. Reports were included in agenda packet; presented by Dr. Browning.

4C: Help Desk Activity Report: January 2004

Total calls for January 2004 numbered 20,498 (82.4% pharmacies, 10.9% clients, 2.2% physicians, 5.8% other). Reports included in agenda packet; presented by Dr. Browning.

4D: Pharmacotherapy Management Activity Update: January 2004

This is a new program that started this year and involves the Waiver Clients. It is a referral program for Waiver Clients who require more than 3 brand medications and 13 total medications. Total clients referred 204; total clients eligible 167; processed 477 petitions; 265 approved, 41 denied, 171 incomplete. Report included in agenda packet; presented by Dr. Flannigan.

4E: DUR Newsletter: Fall 2003

Included in agenda packet; presented by Dr. Flannigan.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: PRESENTATION & DISCUSSION OF COMPREHENSIVE NEUROSCIENCES PRESCRIBER EDUCATION INTERVENTION PROJECT

Jeff Tallent, for Public Comment: *Jeff Tallent, Executive Director for NAMI. I'll be very brief. I hope my advocacy for this presentation that you're about to hear doesn't cast any negative doubt. I had the opportunity two weeks ago to attend a national taskforce of representatives from NAMI and the National Mental Health Association and the New York Psychiatric Association, in Washington, D.C. There were people from all over the country and there was one topic we talked about -- one -- and that was the issue of access to medication for the severely mentally ill. I think the conclusion . . . one of the conclusions that we rapidly came to was that we are far beyond the point where our only action is to come up here and cast rocks at you guys for coming up with ways of trying to contain costs. We're far beyond that. This is got to be an activity in which we're all engaged. And we looked at some of the . . at some of the methods that are out there. One of the . . . the ideas that came up that everyone pretty much agreed needed to be tried was therapy management, no question. Mr. Schafer's presentation is going to be not only an example of, but probably the example that we listened to in the greatest detail while we were there. So I would just tell you that I think what you're . . . I think what you're about to hear, unless Keith has changed this presentation since the last time I heard it, I think, is an example of a good way to start. I think it's a way that we can get engaged in actually reducing the cost of the medication which we know is going up. I think it also gives us the opportunity to at some point, to look at prior authorizing the prescribers, as opposed to prior authorizing the medication itself. It*

gives us a chance to, on a clinical basis, to start making some decisions about who should be doing what to whom, instead of just based on the price of a pill. So, having said that, NAMI is certainly in agreement with the idea that Keith is going to put forth. We hope you give it a shot and we hope to be able to work with this group is making it work because we think it's a real glimmer of hope on this issue that faces us all. That's all I have to say. Thank you very much.

Presentation introduced by Dr. Whitsett; presented by Keith Schafer.

Keith Schafer: *Forgive us for our technology problems here. Your Chair mentioned that I am from Missouri. I actually am from Jefferson City, Missouri which is about 30 miles from the MU Tigers. That's the MU Tigers football and basketball and given what the doctor asked the gentleman from Texas, I would tell you that I really booked we could make both of you angry. Unfortunately we can't and maybe next year. We should have this year, in basketball, but maybe next year. And Mr. Tallent, I will say to you that I will never regret the day that NAMI supports anything that we do because NAMI lives with issues far more seriously than I've ever lived with in my life. I want to try not to talk from there if I can avoid it, and I'm going to be very, very brief because as your Chair mentioned, a number of your members were gracious enough to spend an hour and a half on this process before, so I'm going to go through this very quickly. If I go through too quickly, I'll rely on the Chair to slow me down, but I'm basically just going to give you a bit of a highlight of what we covered earlier. You have handouts by the way, and you can look at this and I'm going to pass over the definitions, but as I talk about these issues, you can refer back to the definitions. Comprehensive Neuroscience Incorporated is a company that is dedicated wholly to improving prescribing practice for people with serious persistent mental illness, which means that we spend almost all of our time focusing on Medicaid eligible individuals, because people with SPMI disorders, inevitably, because of income, wind up on the disabled category of Medicaid. So we spend a lot of time with consumers from states like Oklahoma. We have three goals with the program that we're going to describe to you that we hope to help you do in Oklahoma, and they are in the order of importance, and it's very critical that you understand that. The first goal that we have is try to improve the quality of behavioral health prescribing practice, and to make sure that you understand exactly what is happening in terms of practice patterns in your state as it relates to about 130 behavioral health drugs. Our second is that we want to help you if possible improve patient adherence to their drug plans, and I'll explain a little bit later how we do that. We frankly don't do a lot in that regard, but we have some things that we can help you with and we'll describe those in a second. And third, we can potentially help you reduce the spend rate, and by spend rate, I mean if you . . . if your average spend is 18% per year for behavioral health drugs growth each year, then we may be able to help you reduce that spend rate. We won't make that rate go away and our main objective is not to cut your budget or to save costs. Our main objective is to improve the quality of your prescribing practice. If you believe that improving quality of prescribing practice translates into cost savings, both on the pharmacy side and on the outcome side, then this project will make sense to you. We do basically four things. One is, we profile behavioral health prescribers for deviations from best practice guidelines. These are prescribers of Medicaid behavioral health drugs and we do that on a monthly basis for basically a standard pharmacy claims review . . . Medicaid pharmacy claims review. We engage outlier prescribers through a series of targeted messages. Let me explain to you that outlier prescribers are a very small number of prescribers in your state who significantly deviate or consistently deviate from what are considered national standards of prescribing practice as it relates to how they're prescribing behavioral health. And if they do that on an on-going basis, then we basically help you spend time talking to them about that prescribing pattern and whether or not they should reconsider it. We actually will help this small number of outliers understand that they are not typical of everybody else in the state as most of these prescribers sincerely believe they are. I've met very few prescribers who are deliberately trying to hurt people. I have met a lot of prescribers who sincerely think they're just like most prescribers in their state who are shocked to find that they're not. We basically benchmark prescribers in that regard, and then we provide the funds for you to use peers from your state to work with those outlier prescribers to help them think in a different way about their prescribing pattern. I would stress that these are noted psychiatric peers in your state, not peers from the East Coast or even Missouri. They are people that have to come from Oklahoma. We will also alert prescribers to two things. One is, if a patient fails to fill his medication prescription in the time frame that we believe he should fill it, because we know how many pills he has and how many pills he should have taken by now, then we will alert the prescriber that he may, he or she, may have a patient who has not . . . who is not taking his drugs in the manner that the prescriber has prescribed. About half the time that's true. About half the time, there was another reason that the physician . . .*

Dr. Whitsett: *Excuse me . . . is that across all categories of . . .*

Keith Schafer: *For all behavioral health.*

Dr. Whitsett: *Or do you select antipsychotics and not necessarily . . .*

Keith Schafer: *No. It used to be just antipsychotics but now we do it across all drugs.*

Dr. Whitsett: *For attention deficit disorder, a lot of times, there's a summertime hiatus and all . . .*

Keith Schafer: *Yeah, there's the patterns up and down. We spent a lot of time on antipsychotics first because of their high cost, because of the nature of the patient, but now we can also give you information on other drugs.*

Dr. Whitsett: *Then we decide what to do with it.*

Keith Schafer: *Yeah, yeah. In all cases, by the way, the doctor . . . it's very important what the doctor said. We give you the data, you decide what you want to do with that data and how you want to respond to that data with your prescriber. We'll tell you what our experiences is in other states and you have to make your own decisions about whether that fits. Also I will tell you that there are . . . we always find it in states that we work with, a number of clients or patients who are going to multiple prescribers at the same time and getting drugs from the same class over the same period of time, and we alert both prescribers in a case like that and so they are aware that this is going on. And again, in some cases, it's a logical thing that happens, in some cases it's not. About half the time, the prescribers did not know that. We track this process monthly and that's critically important for you to understand. I've seen a lot of programs that are point in time studies where we'll do the analysis, we will tell the doc, here's what we found, and we don't come back and tell the doc anything else for another year. It doesn't do the doc much good, and it does you no good, because you have no sense of trend. And so this is a trend based program. The kind of indicator categories that we look at, and by the way, your folks looked at this in some detail earlier and asked . . . I mentioned to to them that there are 31 specific indicators falling within these categories and they asked for a list of those indicators and I believe you have that list in front of you now, which will show you basically how we group the things they're going to tell you. We look at therapeutic duplication of atypical antipsychotic drugs. We look at high and low dosing, either based on FDA guidelines or based on the guidelines the state establishes, which is usually higher or lower than FDA. We look at children who are receiving multiple drugs at the same time on the behavioral health side. We look at two or more drugs from the same chemical class. Sometimes, by the way, we look at that and you all will say, if you're like Joe Parks in Missouri, who's the Medical Director DMH, I'm not so worried about that class, I'm very worried about this class and I'm worried about this cross class combination issue. We look at, as I said, the antipsychotics from multiple physicians and we look at patient failure to fill prescriptions. I said to you that what you will find and you may be surprised at this is that the vast majority of your physicians are prescribing well within standards and guidelines. And I stress that in every state we've worked with so far we have not found a deviation from that process. Most prescribers prescribe very carefully inside guidelines. In Missouri, as an example, which was a beta site for this program and it has run for about a year now, about 300 of our prescribers out of 11,000 prescriber sites are responsible for 68% of the hits that we have on the indicators in terms of something that deviated from the guideline. You might wonder how big those hits were. I will tell you that those hits represent about $19 million worth of claims every three months in Missouri, and about 300 prescribers are responsible for about half those hits. So what we try to do is help you hone in on the few prescribers that you may need to spend a lot of time and attention with to impact quality and perhaps even impact cost. It's very difficult for you to hone in on 11,000 prescribers. In Missouri, we have 21,000 with 11,000 prescribing behavioral health drugs. It's almost impossible for you to target your messages to them in a way that'll make a difference. But 300 is a whole different story. You can focus on those folks. Another health plan that we did showed again the same thing. About a 100 out of 2400 prescriber sites accounted for half of the cost. There is a process that we recommend to you. It's a process that joins mental health advocates, clinicians and bureaucrats. And I say that positively. I have been one many years of my life with Medicaid bureaucrats and clinicians. And those entities come to the table together to make decisions about which indicators they want to turn on, which prescribers they want to contact, and how they want to deal with this information. If you don't have both those entities at the table, this program does not work effectively. If you don't have good data to give those entities at the table, this program does not work effectively. This simply talks about what we believe are the keys to success. You can look at that later, but it speaks pretty much to the things that I've talked about so far. Just a quick review of the data and I'm going to jump around here a bit. Let me give you an example of some of the indicators that we have seen in Missouri for quite awhile and impacts on those indicators. In the area of prescribing three or more atypical antipsychotics, now it's typical or atypical antipsychotics simultaneously to a patient, 55% of the prescribers who were doing that practice when we started our baseline review between January and March of last year, stopped doing that by the end of September . . . 55%. And they did not come back on to do it again, so they did not hit our indicators again. 48% of the prescribers who were flagged for giving kids three or more behavioral health drugs simultaneously at the beginning of the project that when we identified them stopped doing that practice by the end of September. And that was a very positive thing for us except that we didn't know it. And the reason we didn't know it is because when we first got our data, we thought we were failing. What our data showed us initially was that we had about 1048 prescribers on the . . . let's just take the three behavioral health drugs for kids . . . when we started in the baseline we had about 1048 prescribers doing that. By September we still had 1024. We figured therefore that our educational messages were absolute failures and then one of our team from Missouri said maybe we should look at the specific prescribers. When we did, we found that those prescribers who had come in in March . . . that 55% of them actually dropped out and stopped doing that behavior by September, but new prescribers started that behavior during the year and so we had to, again, focus on them. Of the prescribers who started that practice in June, the green line, you'll see that they dropped at even a larger or quicker level by the end of September. So you have to be very careful when you look at your data and not just look at the gross data, but you have to look at does that data impact the specific people you've reached. Patients, same issue. 66% of the patients that we identified at the baseline quarter as receiving . . . this was atypical antipsychotics from two prescribers . . . 66% of those individuals were not receiving multiple prescriptions from two*

prescribers by the September quarter. 96% of the patients who had failed to refill their medication within 30 days of the time they ran out of the previous medication were not doing that. In other words, they were refilling their prescriptions at the end of the September quarter. So again, the impacts were significant for the people we reached out to, but as we were reaching out to some people, other people were coming into the system and hitting the indicators and we have to realize that this is a rather continuous process. And this is just a summary to tell you that one of the things that Missouri is excited about is that 300 of the . . . of the outlier prescribers, 300 when we started the program were accountable for 52% of the deviation from the program . . . from the guidelines that we had . . . that we had been reviewing. By the end of December of this year that number 300 prescribers were accountable for 68% of the total deviation, meaning that the number was shrinking. That there were a significant number of prescribers who were now falling back in guidelines and a very small percentage of guys were now responsible for more and more of our deviation. And that's the brief presentation . . . questions if you have them.

Dr. Whitsett: *Questions of Mr. Schafer?*

Dr. Kuhls: *I have just one statement real quickly. Just for our public record since everybody's here this time, can you just repeat what you made in a statement this afternoon about how there's no promise or how you don't think that this is going to change costs? That this program is good in finding prescribers and improving the quality of care, but the total cost to the system . . . can you make the same?*

Keith Schafer: *Yeah, I can make that statement. I think it is a critically important statement and thank you for asking me to do that. First of all, this is a quality improvement effort to improve prescribing practice. If you believe that prescribed . . . that the best possible prescribing practice equates to the most efficient cost, then this program is a program that you'll like a lot from both a quality and a cost perspective, but you should also understand that you are not going to achieve huge amounts of savings from this program simply by doing this program. This is a quality improvement process. With all of the efforts that we have placed in this process, you're still seeing only modest reductions off trend. Now the reductions are significant. Significantly more than the cost of the program, but we do not emphasize cost reduction here. We emphasize quality control here. Alright, if you believe that on the other side, and I think this may be what the Doctors are getting to, if you believe that the best possible prescribing practice that he does results in the best possible outcomes to clients and reduces costs that don't show up in pharmacy, you may well see some significant savings. The problem is you may never know that that happened. So this is a program that focuses on quality control. This is a program depending on how assertive you are that can have a reduction or a depression in your cost growth, but it is not a program designed to cut your budget.*

Dr. Tarasoff: *Just also kind of clarify it so that I'm really clear as well, the source of funding to pay for this for Oklahoma comes from . . .*

Keith Schafer: *Source of funding for all of these states that we do come from PhRMA companies, pharmacy companies. This one comes as an offer from Eli Lilly.*

Board Member: *OK.*

Dr. Whitsett: *It varies from state to state?*

Keith Schafer: *Yep.*

Dr. Whitsett: *And I guess there is some wisdom in that rather than having PhRMA in general do it, it'd be more visibility for specific company, specific state, which is a little worrisome but I think if it were PhRMA there'd be less of a direct possible indirect influence.*

Keith Schafer: *I grew up in the Church of Christ and went to school at Oklahoma Christian College in Edmond and trying to get the Baptists and the Church of Christ and the Methodists all together to fund anything jointly was always extremely difficult.*

Dr. Whitsett: *PhRMA does have money to fund things, I assure you.*

Dr. Tarasoff: *It's again just avoiding, 'cause we mentioned the timeline for implementation, kind of get things going and producing is for26 months. So again, just in terms of avoiding appearance of conflict of interest we're looking at a two to three year commitment.*

Keith Schafer: *Yes. One of the things that we requested from the . . . from any company that funds this process from an unrestricted educational grant, by the way, with no conditions at all on the state or on us. We don't take any position on a particular drug or the state's position on any particular drug, but that we . . . we believe that we had to have, the state had to have significant time to identify the problems they had, to work on the problem they have and to give physicians the opportunity to make a difference. We think that that's at least 24 months. Thank you very much.*

Dr. Whitsett: *Any other questions? Thank you very much.*

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 6: **ANNUAL REVIEW OF ANTI-ULCER MEDICATION UTILIZATION**

Materials included in agenda packet; presented by Dr. McIlvain.

Dr. Whitsett: *If I prescribe Prilosec and it would likely be filled with generic omeprazole and not count as a branded, one of the three?*
Dr. McIlvain: *Right. If they get a prescription for Prilosec and it doesn't specify it has to be the Rx Prilosec, then they can fill it with OTC Prilosec and it does not count as a brand. . . . . We did have a question for you, for the Board on the proton pump inhibitors. Now if they come in asking for, say, Aciphex. If they come in asking for say, Aciphex, and they are, let's see, they have one of these clinical exceptions, do you want us to ask them . . . make them still try omeprazole, OTC omeprazole, or like say, they say they had a GI bleed. Do we still tell them they need to try omeprazole, OTC omeprazole?*
Dr. Kuhls: *The answer's "yes".*
Dr. Whitsett: *Unless they failed it . . . if they failed it, then yeah. But if they haven't failed it . . .*
Dr. McIlvain: *Right. Say they've not tried omeprazole at all recently and they said they had a GI bleed, then are we still supposed to require . . .*
Dr. Whitsett: *I think that now we have the PPI, the Tier-1, that we need to make that official, but that seems like the rational . . .*
Dr. Kuhl: *Yeah, matter of fact my comment was going to be that this first paragraph needs to be rewritten and taken out those clinical exceptions.*
Dr. McIlvain: *Is there anytime at which we should give a Tier-1 drug without a Tier-1 trial? What if they come in and they're already stabilized on something, Aciphex or . . .*
Dr. Whitsett: *The HMO's do it.*
Dr. Kuhls: *Switch 'em?*
Dr. Whitsett: *Yeah.*
Dr. McIlvain: *OK, so no exceptions. Everybody has to try omeprazole, OTC omeprazole at at least 40 mg in the last 150 days before we'll cover something else?*
Dr. Whitsett: *Right.*
Dr. Kuhls: *And the other thing is I just want to make sure that you put in the notes and in the minutes that your additional slide, because the way that this is written you have Tier-1 and you can switch to Tier-2, so the way this is written here is you can go from ranitidine straight to Prevacid and that's not how you had it written up there or how we have it, so this needs to be rewritten to how it actually is. This isn't actually how it is. We have to make sure that before you go to Tier-2 that the Tier-1 Prilosec OTC is used.*
Dr. McIlvain: *And my understanding is that we don't care if they have failed ranitidine recently . . . we just want to see a Prilosec?*
Dr. Kuhls: *Yeah, and you had it up there but it's not here.*
Dr. McIlvain: *That's just the way it used to be, so . . .*
Dr. Kuhls: *Right, that's what I said. This needs to be changed and reflected to how we really have it.*
Dr. Graham: *Do we need to change the days required also? That's another question we have, which right now is 150. Do we want to lower that?*
Dr. Whitsett: *Three months seems like a reasonable time period on that.*
Dr. Graham: *OK, we'll do that.*
Dr. Tarasoff: *I have a question about, this is more of a question for the primary care folks and the pharmacists that may see this. Sometimes I see folks anyway in past treatment in long term care, who are on these for years. And it strikes me that occasionally that someone who had some heartburn one Saturday or Sunday got prescribed this and just got stuck on it. Do we have any tracking on duration of these medications, particularly in populations?*
Dr. Whitsett: *Best I could tell, no one ever stops them on their own. I never heard of that.*
Dr. Tarasoff: *Is that an issue of tracking or is this a big enough budgetary expenditure to bother?*
Dr. McIlvain: *Well we don't exactly track, but what we usually do is, at least in the past what we did was, if they've gotten it, if they've gotten two or three approvals for . . . they are approved for three months at a time, so they'd get two or three of those and we would get, we would send them a message, we give them a one-month approval after they've had several months of continuous use. Give a one-month approval and ask them for more definitive diagnosis and send out a letter to the doctor. Now those letters have needed to be re-drafted since the rule had changed and now it's omeprazole that we're looking for, not H2 blockers, and I don't think the letters have ever been changed yet. I think we're waiting . . . to get them changed. But as soon as those letters get changed, we'll start sending those out again and that way it will alert the doctors.*
The College of Pharmacy recommends that Naprapac™ be placed on Tier II status. We are asking to require trial of omeprazole and generic naproxen. The DUR Board felt this was an appropriate recommendation.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 7: **ANNUAL REVIEW OF GROWTH HORMONE UTILIZATION**

Materials included in agenda packet; presented by Dr. Flannigan.

Dr. Kuhls: Because of the expense and the per diem going up he would like to see if there may be cost savings by using different drugs that are just as efficacious as what has been prescribed for the client (Preferred Drug List).

Dr. Crenshaw: Suggested looking at prescribing patterns of specific physicians.

Dr. Hollen: Asked if the DUR Board was in favor of paying for off-label use of drugs? The consensus of the Board was it depends on the situation, sometimes 'yes' and sometimes 'no'.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 8: **30-DAY NOTICE OF INTENT TO PRIOR AUTHORIZE FORTEO™**

Materials included in agenda packet; presented by Dr. Browning.

The DUR Board wants the COP to research the claims (249) to try and determine what kind of practitioners are using multiple medications or multiple physicians and Dr. Hollen requested the definition of "high risk for fracture".

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **EXECUTIVE SESSION**

The DUR Board met in Executive Session as recommended by the General Counsel and authorized by the Open Meetings Act, 25 Okla. State § 307 (B)(4), (7).

ACTION: NONE REQUIRED.

AGENDA ITEM No. 10: **FUTURE BUSINESS**

10A: Antihistamines Annual Review
10B: Plavix™ Annual Review
10C: Sedative/Hypnotic Annual Review
10D: Synagis™ Utilization Review
10E: Antiviral Utilization Review
10F: Hepatitis C Agents Review
10G: Economic SMAC Report

Materials included in agenda packet; submitted by Dr. Graham.

ACTION: NONE REQUIRED.

AGENDA ITEM No. 11: **ADJOURNMENT**

The meeting was declared adjourned.

APPENDIX B

Activity Audit for

February 01 2004 Through February 29 2004

Date	Antiulcers		Anxiolytic/ Hypnotics		Antihistamine		Growth Hormones		Stimulant		Smoking Cess.		Nsaids		ACE Inhibitors		HTN Combos		Calcium Channel Blockers		Plavix		NPA		Misc		Daily Total
	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	app.	den.	
1	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
2	18	30	114	19	20	24	1	0	61	20	0	0	11	32	5	7	3	0	4	9	24	4	17	1	0	2	426
3	20	49	154	15	25	28	1	0	95	27	0	0	11	29	3	11	3	7	13	24	14	8	16	3	1	5	562
4	16	49	183	17	23	30	2	0	116	34	3	0	16	44	6	14	3	2	11	21	54	5	14	1	1	5	670
5	9	72	162	24	41	29	4	0	115	36	0	0	17	34	6	12	5	4	11	18	55	14	22	3	1	9	703
6	11	38	131	22	22	29	1	0	88	34	0	0	14	41	4	9	4	7	6	13	32	11	10	2	0	2	531
7	13	13	68	11	11	18	0	0	47	21	0	0	9	10	3	5	1	1	0	10	17	7	1	0	0	0	266
8	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
9	13	28	100	18	14	10	0	0	44	15	0	0	9	10	2	8	0	1	4	6	32	6	1	0	0	2	323
10	17	47	164	18	36	36	4	0	110	41	0	0	18	34	3	7	2	4	7	13	43	2	17	0	1	5	629
11	6	50	128	26	31	35	2	1	82	30	0	0	20	40	4	6	6	3	8	15	36	18	23	0	0	5	575
12	7	70	126	25	23	28	1	0	91	26	0	0	13	36	4	18	2	1	7	16	37	10	11	1	1	2	556
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18	2	47	126	8	25	31	3	0	108	26	0	0	19	25	1	14	3	4	8	12	31	6	20	2	0	5	526
19	5	51	104	13	29	22	0	0	94	22	0	0	9	25	4	12	2	6	5	16	36	16	18	2	0	4	495
20	7	71	129	14	45	36	1	0	118	47	0	0	18	26	3	13	4	7	2	11	42	11	13	0	0	3	621
21	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
22	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
23	4	52	97	13	17	18	8	0	69	19	0	0	14	31	1	7	0	5	8	16	23	11	12	2	0	5	432
24	5	57	132	16	33	45	4	0	124	35	0	0	20	19	2	7	3	6	4	17	35	7	15	5	0	3	594
25	10	48	119	19	39	34	1	0	109	17	0	0	15	17	7	10	2	2	9	13	47	4	18	4	1	2	547
26	7	45	93	17	24	25	1	1	81	28	0	0	10	29	2	2	3	4	2	12	21	4	17	2	0	2	432
27	2	49	128	19	26	26	2	0	70	23	0	0	11	20	5	12	3	1	5	16	30	5	28	1	1	2	485
28	2	16	35	22	9	6	0	0	28	9	0	0	6	9	0	0	0	2	0	1	11	2	2	0	0	1	161
29	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

Activity Audit for

February 01 2004 Through February 29 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.	NPA app.	NPA den.	Misc app.	Misc den.	Daily Total
App.	199		2735		556		40		1934		3		307		71		56		128		722		329		10		
Den.		1063		398		600		2		614		0		592		196		74		300		180		35		71	
Average Length of Approvals in Days	93		91		100		145		266		90		355		357		366		357		316		221		194		

Smoking Cessation	1 PA's for Zyban	3 Total PA's Approved
	2 PA's for Nicotine Patch	3 Unique RID's

Changes to existing PA's	344
Total (Previous Year)	11272

Monthly Totals

	Number	Percent of Total
Approved	7106	50.08%
Additional PA's	7	0.05%
SUPER PA's	744	5.24%
Emergency PA's	3	0.02%
Duplicates	564	3.98%
Incompletes	1612	11.36%
Denied *	4152	29.26%
Total	14188	100.00%

Daily Average of 545.69 for 26 Days

*** Denial Codes**

762 = Lack of clinical information	39.21%
763 = Medication not eligible	2.19%
764 = Existing PA	10.21%
772 = Not qualified for requested Tier	7.35%

SUPER PA's

Early Refill Attempts	64055
Dosing Change	507
lost/stolen/broke	84
Other	90
wrong DS	63

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)

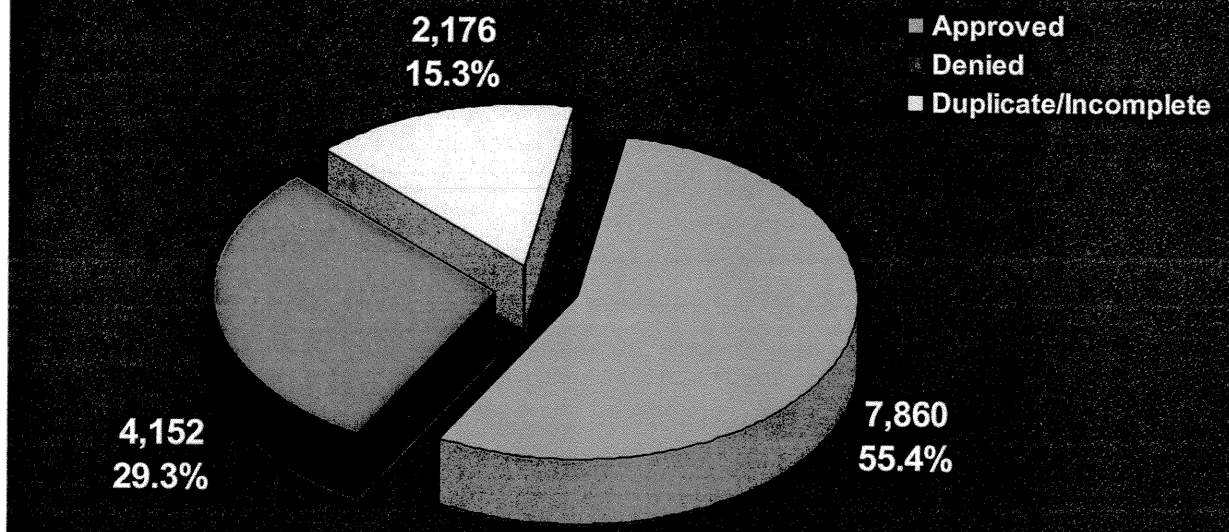
Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)

PRIOR AUTHORIZATION ACTIVITY AUDIT

Monthly Totals

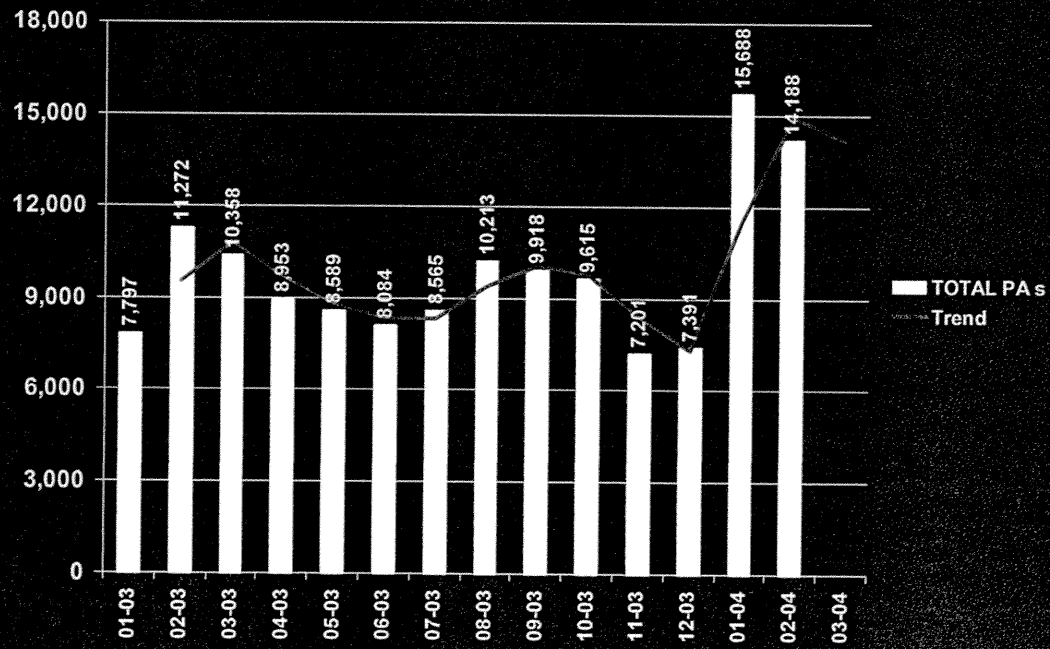
MONTH	1999 Total *(approved/ duplicates/ denied)*	2000 Total *(approved/ duplicates/ denied)*	2001 Total *(approved/ duplicates/ denied)*	2002 Total *(approved/ duplicates/ denied)*	2003 Total *(approved/ duplicates/ denied)*	2004 Total *(approved/ duplicates/ denied)*
January	4,124	8,669	9,296	8,427	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	
April	3,867	6,390	7,676	13,381	8,953	
May	3,959	6,711	7,980	12,082	8,589	
June	3,884	6,565	7,249	8,550	8,084	
July	3,523	6,181	8,133	8,775	8,565	
August	10,676	7,183	8,195	9,353	10,213	
September	8,387	6,585	7,438	9,793	9,918	
October	3,863	6,140	7,956	11,584	9,615	
November	3,919	6,961	7,949	7,921	7,201	
December	3,953	6,206	6,385	4,867	7,391	
Calendar Year Total	**57,553**	**83,256**	**93,199**	**107,661**	**107,956**	**29,876**

PRIOR AUTHORIZATION ACTIVITY REPORT
February 2004



PHARMACY Management Consultants

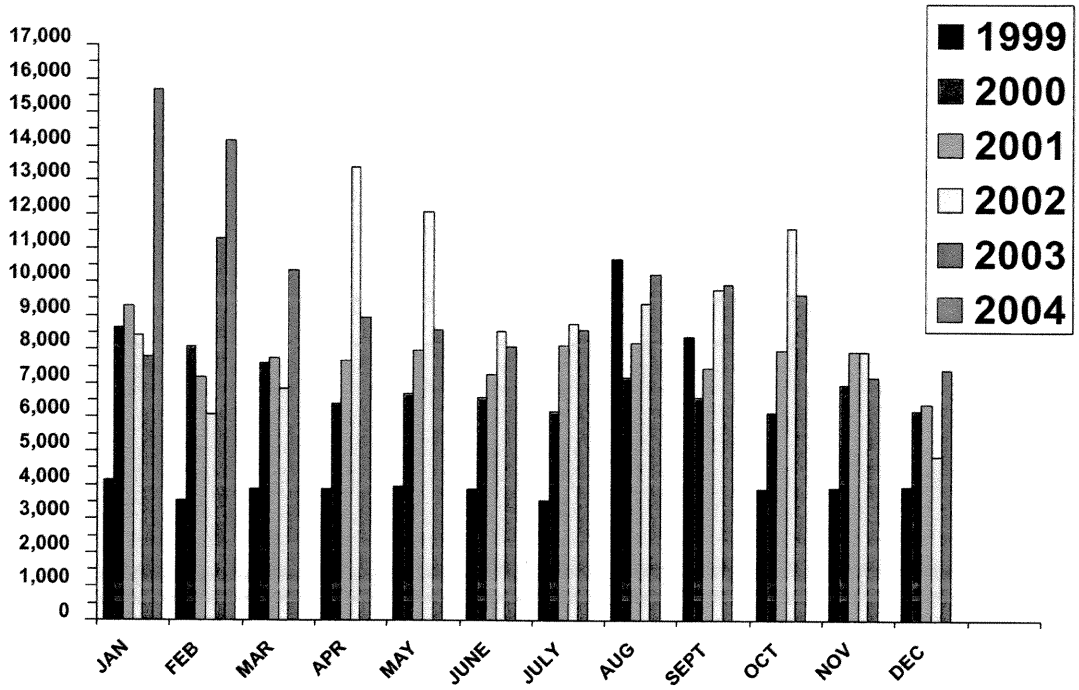
PRIOR AUTHORIZATION REPORT
February 2003 – February 2004



PHARMACY Management Consultants

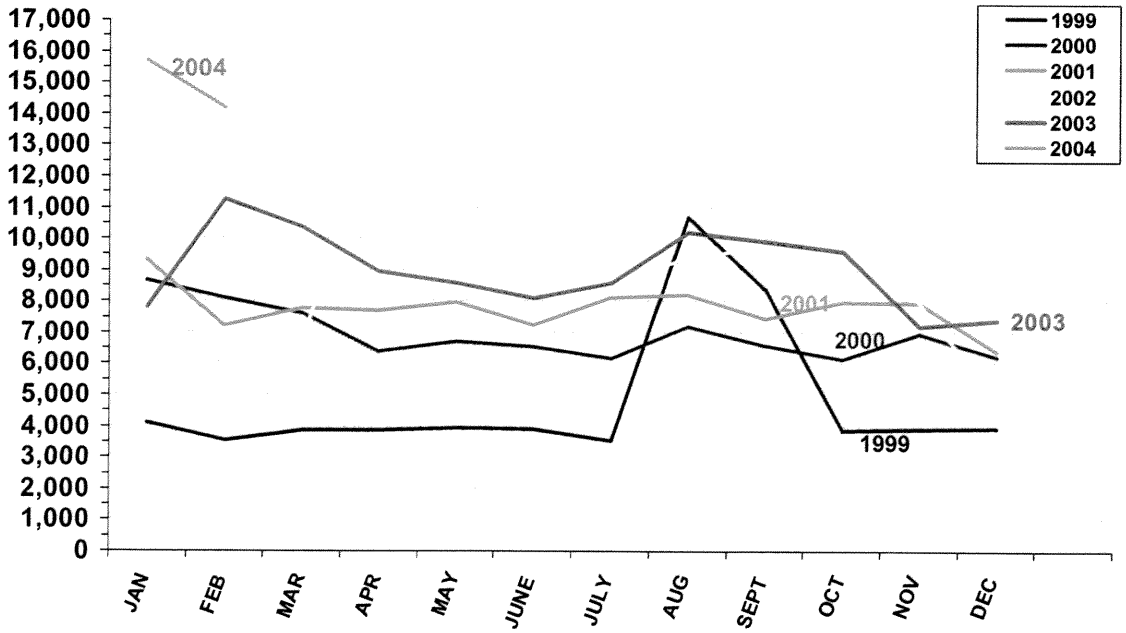
Monthly PA Activity

Calendar Years 2000-2004



Monthly PA Activity

Calendar Years 2000-2004



CALL VOLUME - FEBRUARY 2004

FEB 04	CALLER					ISSUE					TYPE OF CALL							RESOLUTION						
																				Resolved				
	Call Volume	Physician	Pharmacies	Clients	Other	Eligibility	Claims	PA Issue	SMAC	Other	Regular	Callback	Transferred Pharmacist	Transferred Supervisor	Proactive	ProDUR	Other	Helpdesk Resolved	Helpdesk PA	OHCA	Reversals/ Adjustments	EDS	Customer Service	Provider Contracts
1	132	2	124	4	2	27	85	1		19	130	1	0	0	0	0	1	132	0	0	0	0	0	0
2	1014	8	885	95	26	233	632	77	0	72	982	11	1	1	1	10	8	1006	4	0	4	0	0	0
3	890	7	706	86	91	197	418	147	0	128	782	74	1	0	2	14	17	887	3	0	0	0	0	0
4	849	9	694	83	63	201	425	145	0	78	775	56	1	0	2	4	11	847	1	0	1	0	0	0
5	815	10	594	77	134	184	337	196	0	98	668	122	2	0	1	10	12	808	2	0	3	0	2	0
6	687	7	561	62	57	160	345	117	0	65	612	45	1	0	1	20	8	680	3	0	4	0	0	0
7	149	0	144	4	1	84	32	5	0	28	148	0	0	0	0	0	1	148	1	0	0	0	0	0
8	66	1	64	1	0	41	18	1	0	6	66	0	0	0	0	0	0	66	0	0	0	0	0	0
9	887	4	743	80	60	204	497	85	0	101	812	33	1	0	1	14	26	881	3	0	3	0	0	0
10	789	10	677	64	38	203	403	91	0	92	744	22	0	0	2	12	9	786	2	0	1	0	0	0
11	838	18	670	87	63	184	460	131	0	63	760	53	0	0	1	15	9	832	3	0	3	0	0	0
12	804	17	634	73	80	165	372	160	0	107	695	67	1	0	4	20	17	797	2	0	5	0	0	0
13	743	12	643	53	35	123	488	71	0	61	683	33	2	0	1	10	14	742	1	0	0	0	0	0
14	183	0	176	6	1	36	83	12	1	21	181	2	0	0	0	0	0	183	0	0	0	0	0	0
15	55	0	53	2	0	9	41	3	0	2	55	0	0	0	0	0	0	55	0	0	0	0	0	0
16	607	3	558	37	9	162	259	63	0	80	569	2	1	0	3	11	21	605	2	0	1	0	0	0
17	808	8	572	82	146	241	285	184	0	98	656	122	1	0	5	12	12	798	3	0	7	0	0	0
18	850	18	715	66	51	189	475	109	0	77	785	37	5	0	3	7	13	843	2	0	5	0	0	0
19	762	9	611	68	74	184	437	143	0	98	672	62	1	0	0	15	12	755	5	0	2	0	0	0
20	699	13	582	51	53	123	413	105	0	58	636	49	1	0	1	3	9	693	4	0	2	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	65	0	60	3	2	4	54	1	0	6	62	3	0	0	0	0	0	65	0	0	0	0	0	0
23	774	8	667	86	13	229	366	85	0	94	753	4	1	0	1	11	4	771	3	0	0	0	0	0
24	762	10	593	89	70	215	307	158	0	82	671	55	3	0	1	11	18	758	4	0	0	0	0	0
25	805	16	625	79	85	198	381	133	1	92	618	70	0	0	1	11	6	804	1	0	0	0	0	0
26	775	14	636	75	50	185	388	117	0	85	715	39	1	0	1	11	8	768	1	0	4	0	0	2
27	759	16	612	82	49	212	328	121	0	98	693	34	2	1	1	13	15	744	2	3	3	0	6	0
28	235	3	186	7	1	55	117	8	0	55	177	2	0	0	0	0	0	235	0	0	0	0	0	0
29	55	1	37	0	0	7	38	1	0	9	54	1	0	0	0	0	0	55	0	0	0	0	0	0
Total	**16,857**	**224**	**13,822**	**1,502**	**1,254**	**4,055**	**8,484**	**2,470**	**2**	**1,873**	**15,154**	**999**	**26**	**2**	**33**	**234**	**251**	**16,744**	**52**	**3**	**48**	**0**	**8**	**2**
Percentage	**100.00%**	**1.33%**	**82.00%**	**8.91%**	**7.44%**	**24.06%**	**50.33%**	**14.65%**	**0.01%**	**11.11%**	**89.90%**	**5.93%**	**0.15%**	**0.01%**	**0.20%**	**1.39%**	**1.49%**	**99.33%**	**0.31%**	**0.02%**	**0.28%**	**0.00%**	**0.05%**	**0.01%**

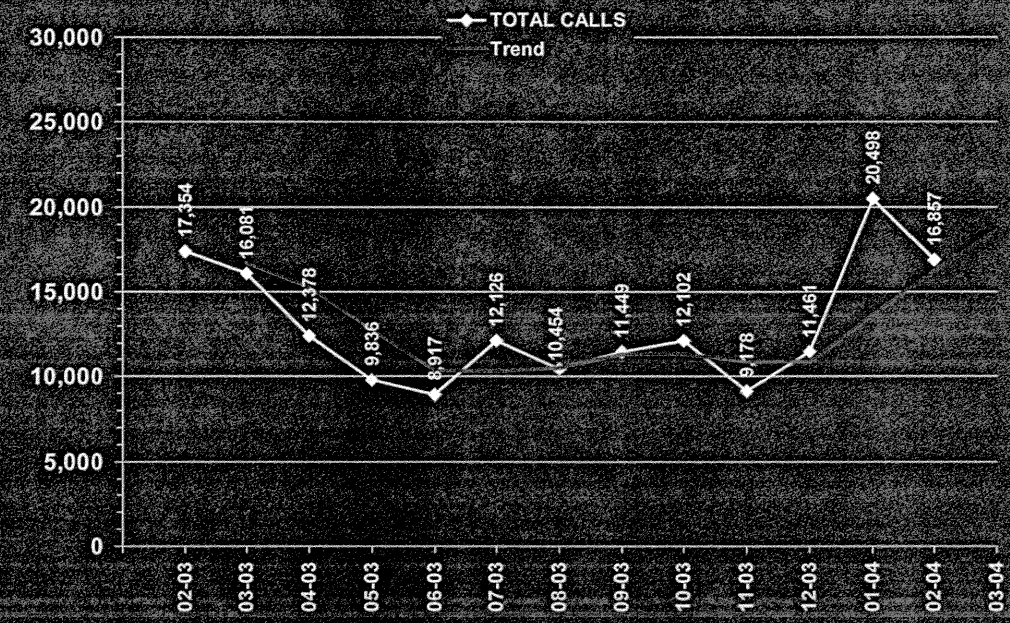
CALL VOLUME

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	
April	* 0	3,337	4,556	8,047	12,378	
May	* 0	3,804	5,540	7,586	9,836	
June	* 0	2,820	4,982	6,368	8,917	
July	* 0	3,242	5,465	7,651	12,126	
August	3,883	4,333	6,881	7,629	10,454	
September	2,360	4,015	5,145	8,664	11,449	
October	1,963	4,398	5,912	9,608	12,102	
November	1,721	4,216	6,011	6,627	9,178	
December	2,475	3,804	5,314	11,710	11,461	
Calendar Year Total	**12,402**	**45,158**	**63,772**	**91,092**	**154,835**	**37,355**

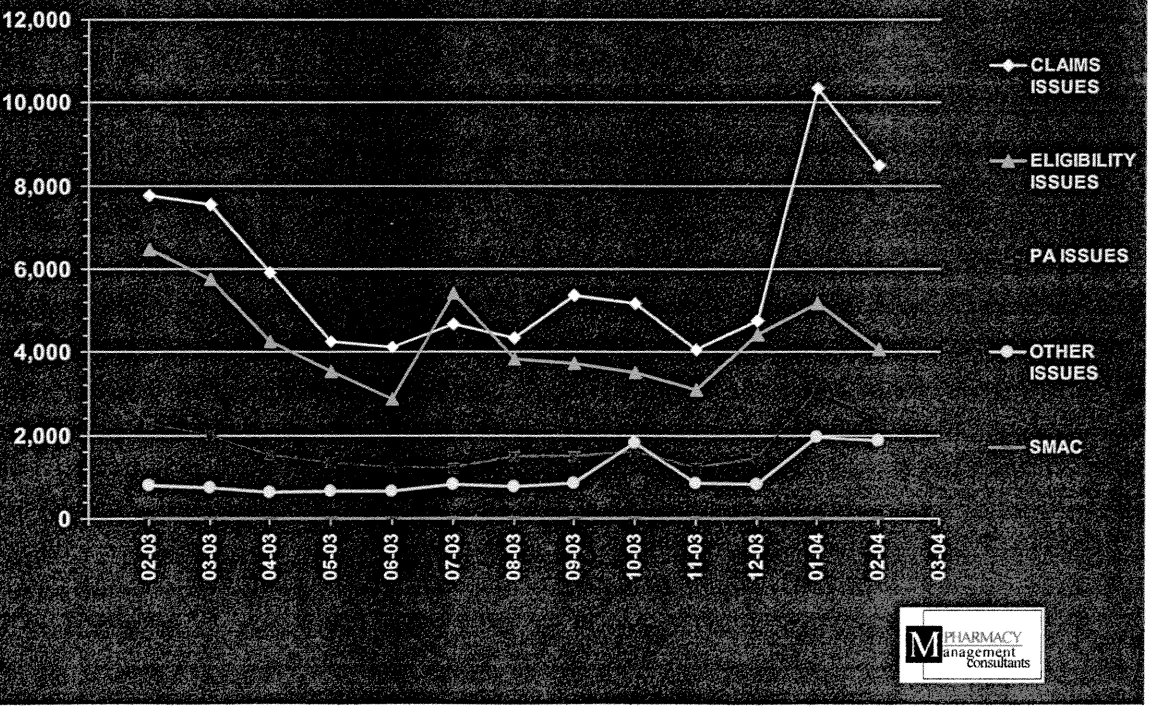
* Help Desk Call Center implemented in August 1999.

CALL VOLUME MONTHLY REPORT
February 2003 – February 2004



PHARMACY management consultants

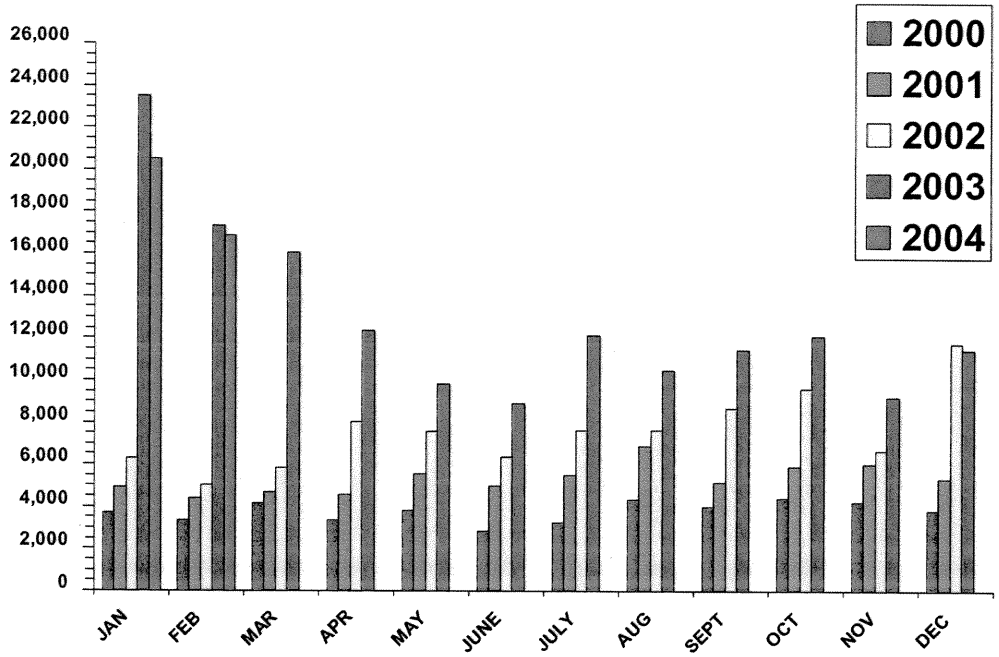
CALL VOLUME ISSUES
February 2003 – February 2004



PHARMACY management consultants

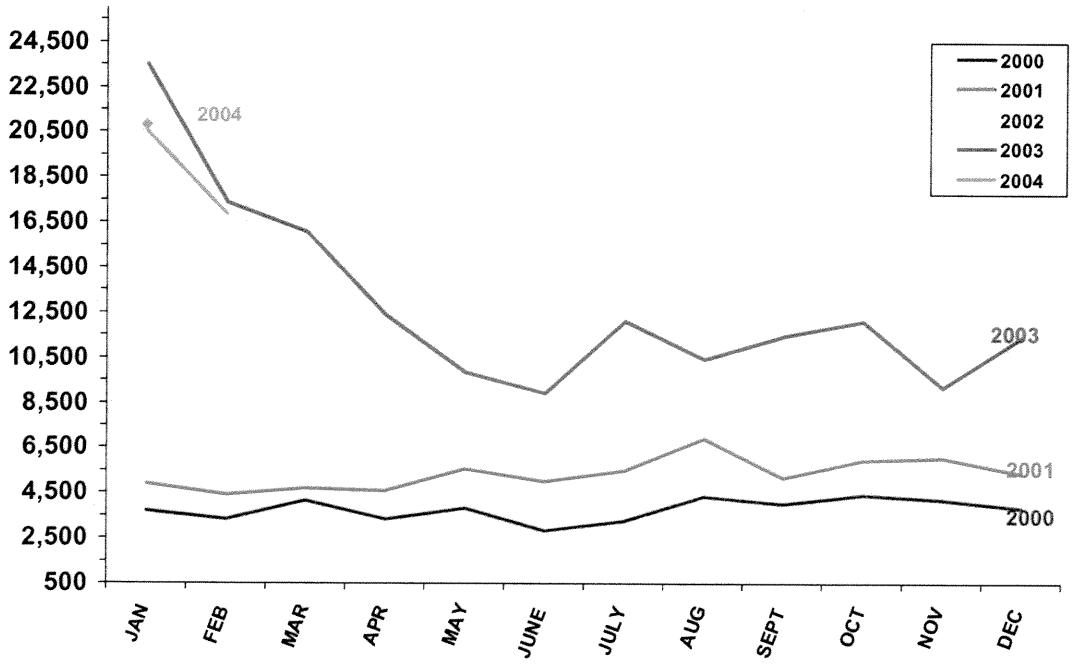
Monthly Call Volume

Calendar Years 2000-2004



Monthly Call Volume

Calendar Years 2000-2004



APPENDIX C

Vote to Prior Authorize Forteo®

The College of Pharmacy recommends prior authorizing Forteo.

Prior authorization critera:

- Postmenopausal women at high risk for fracture (T-score at or below -2.5) or that cannot tolerate, are allergic to, or have failed to improve while on other agents.
- Men with primary or hypogonadal osteoporosis.
- Appropriate ICD-9 code.
- No concurrent use of Forteo® with other agents until/when more information is available.
- Minimum 12 month trial with any one other agent (unless contraindicated, intolerant, or allergic) and a BMD (T-score at or below -2.5) test within the last month (results indicated on petition).
- PA approval for one month's supply per fill for duration of 1 year. With a maximum renewal period of 2 years.

APPENDIX D

Prior Authorization Annual Review - Fiscal Year 2003
Non-Sedating Antihistamines (NSA)
Oklahoma Medicaid
March 2004

Current Definition of NSA Prior Authorization Category*

- Legend non-sedating antihistamine only products are covered after a previous trial failure with an over-the-counter antihistamine. A 14 day trial of over-the-counter loratadine is required prior to coverage of a legend only product for all age groups.
    - Trial should have been in the last month and be of adequate dose and duration,
    - Over-the-counter loratadine is a covered benefit for clients under the age of 21 years without prior authorization, and
    - For clients 21 years of age or greater, loratadine is available with prior authorization AFTER documented over-the-counter failure of a non-loratadine product.
- For clients six months to two years of age, cetirizine syrup is available without prior authorization.
- Diagnosis must be for a chronic allergic condition.
- Prior authorization will not be approved for a time period greater than 90 days for clients without a diagnosis which requires continuous coverage.

*Current definition became effective August 2003.

Changes to Category for Fiscal Year '03

As of January 1, 2003, the following changes were made to this category under emergency rule:

- All age groups are subject to the prior authorization process.
- Combination products with decongestants are no longer covered.
- A trial of OTC loratadine is required for all age groups. (This is a covered benefit for children < 21 years of age without prior authorization.)

Utilization

For the period of July 2002 through June 2003, a total of 35,081 clients received non-sedating antihistamines and combination products through the Medicaid fee-for-service program.

Product		# of Claims	Total Units	Total Days	Units/Day	Total Cost	Per Diem
Rx	*Single*	29,842	1,067,007	959,167	1.11	$ 2,175,005.52	$ 2.27
	Liquid	20,880	2,775,019	523,824	5.30	$ 771,200.67	$ 1.47
	Combination	5,389	246,932	146,599	1.68	$ 297,926.83	$ 2.03
OTC	*Single*	12,299	347,349	345,286	1.01	$ 350,581.89	$ 1.02
	Liquid	6,388	798,110	154,204	5.18	$ 78,071.43	$ 0.51
	*Combination**	215	5,559	5,166	1.08	$ 6,753.82	$ 1.31
All Products		**75,013**	**5,239,976**	**2,134,246**		**$ 3,679,540.16**	

*OTC Combination products were paid for a limited time due to programming error.

Total Cost FY '03	**$3,679,540.16**
Total Cost FY '02	*$4,853,581.41*
Total Claims FY '03	**75,013**
Total Claims FY '02	*88,253*
Per Diem FY '03	**$1.72**
Per Diem FY '02	*$1.95*

Market share for select products.

Brand Name	Total Days/ Brand FY '02	% Share/ Brand FY '02	Total Days/ Brand FY '03	% Share/ Brand FY '03
Allegra	351,052	14.09%	255,589	11.98%
Clarinex	30,348	1.22%	68,413	3.21%
Claritin	1,102,931	44.28%	999,581	46.84%
Zyrtec	1,006,496	40.41%	810,663	37.98%

Total petitions submitted in for this category during specified time period: 12,132.

Approved *5,843*
Denied 4,900
Incomplete 1,389
*1,274 denied or incomplete petitions were subsequently approved.

Age/Gender FY03

Age	Female	Male	Totals
0 to 10	10,596	12,021	22,617
11 to 20	5,570	4,776	10,346
21 to 34	240	131	371
35 to 49	277	180	457
50 to 64	322	102	424
65 to 79	431	110	541
80 to 94	256	50	306
95 and Over	12	7	19
Totals	**17,704**	**17,377**	**35,081**

Recommendations

The College of Pharmacy has the following recommendations:

- Continuation of the current criteria and tier structure.
- Continued education to providers regarding available products for this category.

APPENDIX E

Prior Authorization Annual Review - Fiscal Year 2003
Plavix®
Oklahoma Medicaid
March 2004

Definition of Prior Authorization Category for FY '03

Prior to February 3, 2003, Plavix was available with out regard to the scope of use.

Fiscal Year '03 Changes

As of February 3, 2003, Plavix® required prior authorization for all clients. Plavix therapy was approved for those clients meeting approved diagnostic criteria that had failed aspirin trials or had a documented allergy to aspirin. The approved diagnoses are as follows:

- Recent stroke
- Recent myocardial infarction
- Established peripheral artery disease
- Acute coronary syndrome (unstable angina/non-Q-wave MI)
- Percutaneous coronary intervention with stent placement

Clients, with the exception of stent placement, are eligible for up to a year of therapy per authorization. Post stent placement clients are eligible for up to 90 days of therapy.

Utilization

For the period of July 2002 through June 2003, a total of 6,396 clients received Plavix® through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Clients	Per Diem
Plavix® 75 mg	29,813	1,141,839	1,123,541	1.02	$ 4,007,931.48	6,396	$ 3.57

Total Cost FY '03	**$4,007,931.48**
Total Cost FY '02	*$3,527,554.85*
Total Claims FY '03	**29,813**
Total Claims FY '02	*32,605*
Total Clients FY '03	**6,396**
Total Clients FY '02	*5,987*
Total Units FY'03	**1,141,839**
Total Units FY'02	*1,095,793*

Per Diem FY '03 **$3.57**
Per Diem FY '02 *$3.25*

During FY'03 there was a $0.24/unit cost increase in Plavix. This, in addition to the small increase in the number of clients for the year, is the reason for the overall increase in cost for the fiscal year.

Percent Increase Compared to Previous FY				
	# Clients	# Units	# Days	Total Cost
FY'03	6.8%	4.2%	3.6%	13.6%
FY'02	29.0%	38.6%	39.1%	54.0%

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

Approved *3,572*
Denied 1,644
Incomplete 1,089

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

Age	Female	Male	Totals
0 to 9	2	1	3
10 to 19	2	3	5
20 to 34	16	8	24
35 to 49	205	150	355
50 to 64	824	479	1,303
65 to 79	1,759	758	2,517
80 to 94	1,684	371	2,055
95 and Over	112	22	134
Totals	**4,604**	**1,792**	**6,396**

Changes in Utilization Since Implementation

Total Plavix® Cost Feb '03 thru July '03 **$1,543,078.08**
Total Plavix® Cost Aug '02 thru Jan '03 *$2,373,909.51*
Total Plavix® Claims Feb '03 thru July '03 **10,161**
Total Plavix® Claims Aug '02 thru Jan '03 *18,329*

Market Share Shift by Therapy Days for Therapeutic Category

Drug Name	Total Days/ Product Aug 02 – Jan 03	% Share/ Product Aug 02 – Jan 03	Total Days/ Product Feb 03 – Jul 03	% Share/ Product Feb 03 – Jul 03	Percent Change
Clopidigrel	685,567	79.75%	405,148	68.16%	**-11.59%**
Dipyridamole	35,605	4.14%	32,766	5.51%	**1.37%**
Ticlopidine	11,044	1.28%	9,068	1.53%	**0.25%**
Cilostazol	83,551	9.72%	80,472	13.54%	**3.82%**
Anagrelide	2,674	0.31%	2,465	0.41%	**0.10%**
Dipyridamole/Apririn	41,238	4.80%	64,475	10.85%	**6.05%**

Recommendations

The college of pharmacy recommends continuation of the current criteria for this category.

APPENDIX F

Prior Authorization Annual Review - Fiscal Year 2003
Anxiolytics/Hypnotics
Oklahoma Medicaid
March 2004

Definition of Prior Authorization Category for FY '03

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.

Fiscal Year '03 changes

Xanax XR was added for prior authorization:

- With an FDA approved diagnosis of panic disorder (w/wo agoraphobia).
- Previously stabilized on alprazolam at requested dose of Xanax XR.
- 8 week authorization per request.

Utilization

28,183 clients received benzodiazepines/hypnotics through the Medicaid fee-for-service program for fiscal year 2003.

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Alprazolam 0.25mg	9,697	543,198	230,342	2.36	$52,270.42	4,085	$0.23
Xanax 0.25mg	58	3,640	1,309	2.78	$3,054.25	17	$2.33
Alprazolam 0.5mg	10,843	696,836	270,820	2.57	$64,351.88	4,827	$0.24
Xanax 0.5mg	73	4,942	1,970	2.51	$5,364.48	25	$2.72
Alprazolam 1mg	8,190	654,584	223,858	2.92	$58,805.17	3,444	$0.26
Xanax 1mg	83	6,316	2,264	2.79	$7,388.50	37	$3.26

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Alprazolam 2mg	2,256	194,438	63,389	3.07	$26,078.16	936	$0.41
Xanax 2mg	15	1,425	407	3.50	$2,862.49	8	$7.03
Alprazolam 1mg/ml	1	60	40	1.50	$94.76	1	$2.37
Xanax XR 0.5mg	3	150	90	1.67	$294.25	3	$3.27
Xanax XR 1mg	5	270	150	1.80	$654.33	5	$4.36
Xanax XR 3mg	2	60	60	1.00	$285.46	1	$4.76
CDP 5mg	300	16,992	7,835	2.17	$3,454.94	95	$0.44
CDP 10mg	1,070	76,043	28,880	2.63	$8,504.23	460	$0.29
Librium 10mg	1	100	25	4.00	$10.39	1	$0.42
CDP 25mg	619	43,444	14,523	2.99	$5,247.73	297	$0.36
Cloraze DIP 3.75mg	1,439	91,229	39,040	2.34	$30,243.80	489	$0.77
Tranxene 3.75mg	10	614	302	2.03	$708.49	6	$2.35
Cloraze Dip 7.5mg	1,456	100,422	41,902	2.40	$33,065.20	507	$0.79
Tranxene 7.5mg	49	3,969	1,323	3.00	$8,703.24	13	$6.58
Cloraze Dip 15mg	275	20,169	8,312	2.43	$25,948.67	78	$3.12
Tranxene T 15mg	15	1,500	513	2.92	$4,546.59	4	$8.86
Tranxene-S 11.25mg	1	30	30	1.00	$148.90	1	$4.96
Tranxene-S 22.5mg	17	3,540	430	8.23	$9,847.86	3	$22.90
Diazepam 2mg	1,659	96,890	40,226	2.41	$9,590.83	689	$0.24
Diazepam 5mg	6,582	367,523	152,213	2.41	$38,362.88	3,061	$0.25
Diazepam 10mg	5,326	363,753	132,587	2.74	$41,766.74	2,354	$0.32
Diazepam 5mg/ml con	18	1,084	347	3.12	$623.36	8	$1.80
Diazepam 1mg/ml sol	170	83,105	2,745	30.28	$3,995.65	68	$1.46
Diazepam 5mg/ml inj	149	1,690	518	3.26	$1,746.15	114	$3.37
Ativan 0.5mg	57	3,860	1,481	2.61	$2,835.95	19	$1.91
Lorazepam 0.5mg	12,774	713,166	298,502	2.39	$208,084.88	4,743	$0.70
Ativan 1mg	55	4,169	1,598	2.61	$3,711.82	25	$2.32
Lorazepam 1mg	10,836	666,370	260,644	2.56	$229,298.58	4,216	$0.88
Ativan 2mg	14	730	368	1.98	$950.08	6	$2.58
Lorazepam 2mg	2,646	156,002	65,957	2.36	$66,927.85	1,045	$1.01
Lorazepam 2m/ml Con	92	2,655	1,304	2.04	$3,372.28	68	$2.59
Ativan 2mg/ml inj	830	4,089	2,089	1.96	$29,046.22	512	$14.00
Lorazepam 2mg/ml inj	259	3,652	1,193	3.06	$7,883.65	173	$6.61
Ativan 4mg inj	1	100	30	3.33	$693.69	1	$23.12
Lorazepam 4mg/ml	1	5	10	0.50	$24.65	1	$2.47
Oxazepam 10mg	491	34,507	12,408	2.78	$22,196.59	151	$1.79
Oxazepam 15mg	395	29,327	11,651	2.52	$19,327.92	132	$1.66
Oxazepam 30mg	68	5,141	1,900	2.71	$6,188.77	23	$3.26
Serax 30mg	3	270	90	3.00	$356.27	1	$3.96
Serax 15mg	9	303	229	1.32	$383.02	4	$1.67
Estazolam 1mg	137	3,531	3,305	1.07	$2,586.22	49	$0.78
Prosom 1mg	5	127	127	1.00	$109.35	3	$0.86
Estazolam 2mg	174	5,939	5,247	1.13	$4,497.18	60	$0.86
Prosom 2mg	5	105	135	0.78	$121.30	3	$0.90
Flurazepam 15mg	114	4,112	2,913	1.41	$673.11	62	$0.23
Dalmane 30mg	3	67	67	1.00	$87.41	3	$1.30
Flurazepam 30mg	267	8,629	7,959	1.08	$2,090.51	124	$0.26
Doral 15mg	8	420	420	1.00	$1,251.15	6	$2.98
Restoril 7.5mg	876	25,685	24,648	1.04	$46,330.13	298	$1.88
Temazepam 7.5	134	4,042	3,620	1.12	$3,146.90	82	$0.87

Product	# of Claims	Total Units	Total Days	Units/Day	Total Cost	Total Clients	Per Diem
Restoril 15mg	16	820	460	1.78	$1,444.96	7	$3.14
Temazepam 15mg	5,754	186,311	163,998	1.14	$41,014.18	2,593	$0.25
Restoril 30mg	24	780	720	1.08	$849.60	11	$1.18
Temazepam 30mg	4,655	150,926	144,815	1.04	$36,668.94	2,047	$0.25
Triazolam 0.125mg	64	1,564	1,367	1.14	$897.22	37	$0.66
Halcion 0.25mg	53	2,224	1,704	1.31	$2,627.83	22	$1.54
Triazolam 0.25mg	558	17,532	14,611	1.20	$6,297.02	246	$0.43
Sonata 5mg	422	13,411	11,715	1.14	$25,388.49	192	$2.17
Sonata 10mg	1,170	37,375	32,579	1.15	$84,308.30	577	$2.59
Ambien 5mg	7,766	225,445	210,886	1.07	$446,349.03	3,211	$2.12
Ambien 10mg	11,659	361,597	351,985	1.03	$857,276.81	4,705	$2.44
Total	**112,777**	**6,053,005**	**2,909,185**		**$2,613,317.69**	**28,183***	**$0.90****

*Total unduplicated clients for FY03, **Total cost/total days

Total Cost FY '03 **$2,613,317.69**
Total Cost FY '02 *$2,767,008.30*
Total Claims FY '03 **112,777**
Total Claims FY '02 *117,170*
Total Clients FY '03 **28,183**
Total Clients FY '02 *26,698*
Per Diem FY '03 **$0.90**
Per Diem FY '02 *$0.93*

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

Approved 26,509
Denied 4,635
Incomplete 1,207

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

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**

FY '02

Age	Female	Male	Totals
0 to 9	152	220	37
10 to 19	608	491	109
20 to 34	2010	729	273
35 to 49	3320	1825	514
50 to 64	3445	1703	514
65 to 79	4991	1681	667
80 to 94	4247	870	511
95 and Over	360	46	40
Totals	**19,133**	**7,565**	**26,69**

Recommendations

The college of pharmacy recommends continuation of the current criteria for this category for Fiscal year 2004.

- However, the COP would like to see decreased use in the elderly. Therefore, we would recommend that the "LTC" population be included within the Therapy Management Program in the near future.

- We would also recommend that client's taking stimulants should not take anxiolytics/hypnotics concurrently.

APPENDIX G

SYNAGIS (palivizumab)

Oklahoma Medicaid

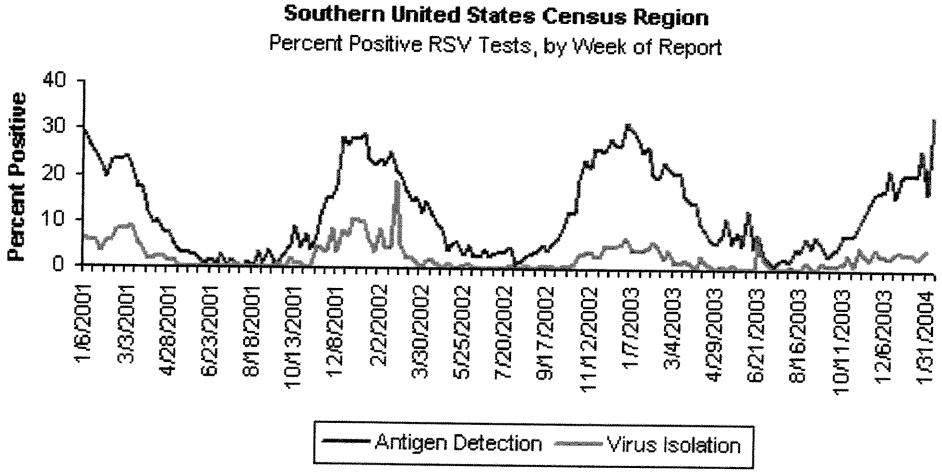
March, 2004

- **Introduction**
  Synagis (palivizumab) is a recombinant humanized monoclonal antibody used in the prevention of respiratory syncytial virus (RSV) infection in high-risk infants and children. It is NOT indicated for the treatment of RSV infection.

- **Product Information**
  Synagis is available as a sterile lyophilized powder for reconstitution for injection. It is supplied in single-use 50 mg and 100 mg vials.

- **Dosing information**
  The recommended dose is 15 mg/kg as an IM injection given once a month during RSV season (usually November to April in Oklahoma). Synagis should be started just prior to the beginning of RSV season. Synagis does not interfere with routine vaccinations.

- **Epidemiology**
  RSV is the pathogen that causes seasonal outbreaks of a lower respiratory illness each year. While this is a ubiquitous viral agent, in children with certain risk factors (e.g. prematurity, CLD), the illness can be very severe.



Information from National Respiratory and Enteric Virus Surveillance System (NREVSS),

American Academy of Pediatrics guidelines (2003)

- RSV prophylaxis is recommended for:
  - Infants and children less than 2 years of age with Chronic Lung Disease (CLD) who have required medical treatment (O_2, bronchodilator, diuretic, or corticosteroid therapy) for CLD in the 6 months prior to RSV season.

- Infants born at 28 weeks gestation or earlier, in first RSV season that occurs in the first 12 months of life. Treatment should continue through the entire RSV season.
- Infants born at 29-32 weeks gestation, in first RSV season that occurs in the first 6 months of life. Treatment should continue through the entire RSV season.
- Infants, up to 6 months old at the start of RSV season, born at 32-36 weeks gestation, who have 2 or more of the following risk factors: *child care attendance, school-aged siblings, exposure to environmental air pollutants, congenital abnormalities of the airway, and severe neuromuscular disease.*
- Children up to 24 months old with hemodynamically significant cyanotic and acyanotic congenital heart disease.
- Infants up to 12 month with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medication to control congestive heart failure

➢ Possible benefit
- Children with severe immunodeficiencies
- Children with cystic fibrosis

➢ Not recommended
- Treatment of RSV disease
- Prophylaxis against nosocomial RSV
- Infants/children with hemodynamically insignificant heart disease
- Infants with lesions adequately corrected by surgery (unless requiring medication for congestive heart failure
- Infants with mild cardiomyopathy not receiving medical therapy

➢ **General Usage**

Total paid September 2002 - May 2003: $3,888,433.15
Total Paid: September 2001 – May 2002 *$2,575,256.27*

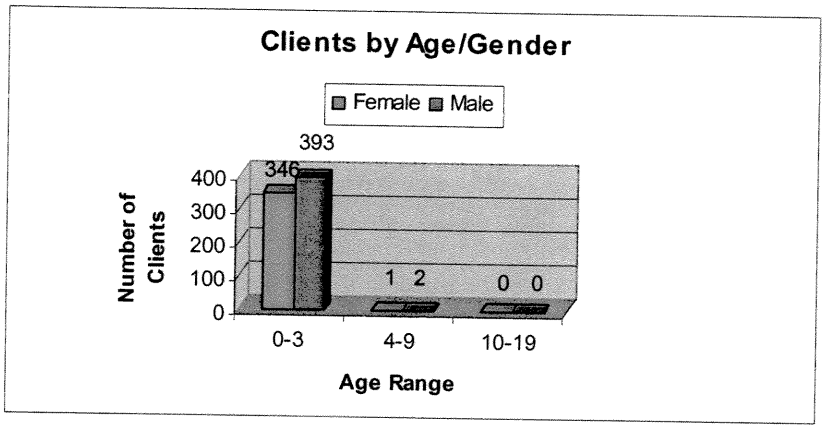
Total # of clients Sept 2002 – May 2003: 742 clients
Total Clients: Sept 2001 - May 2002 *461 clients*

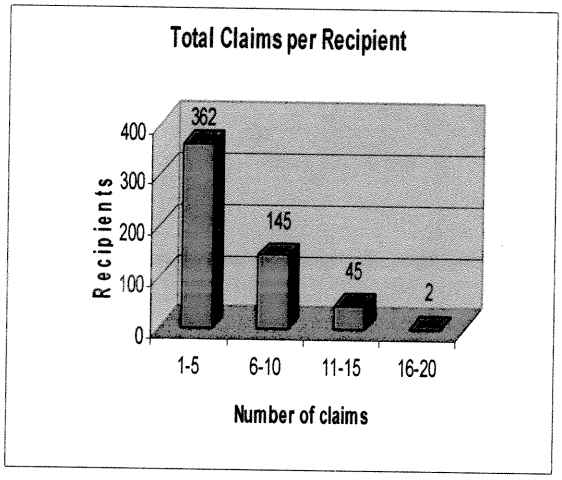
Total # of claims Sept 2002 – May 2003: 3,314 claims
Total Claims: Sept 2001 – May 2002 *2,202 claims*

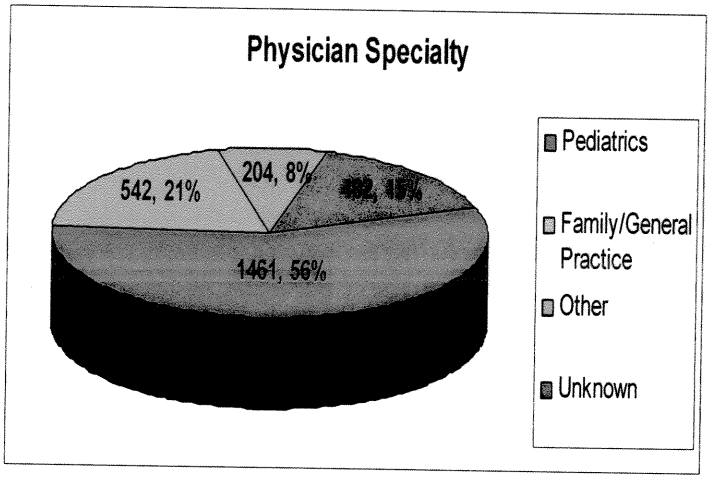
Oklahoma Medicaid Utilization 9/1/02-5/31/03

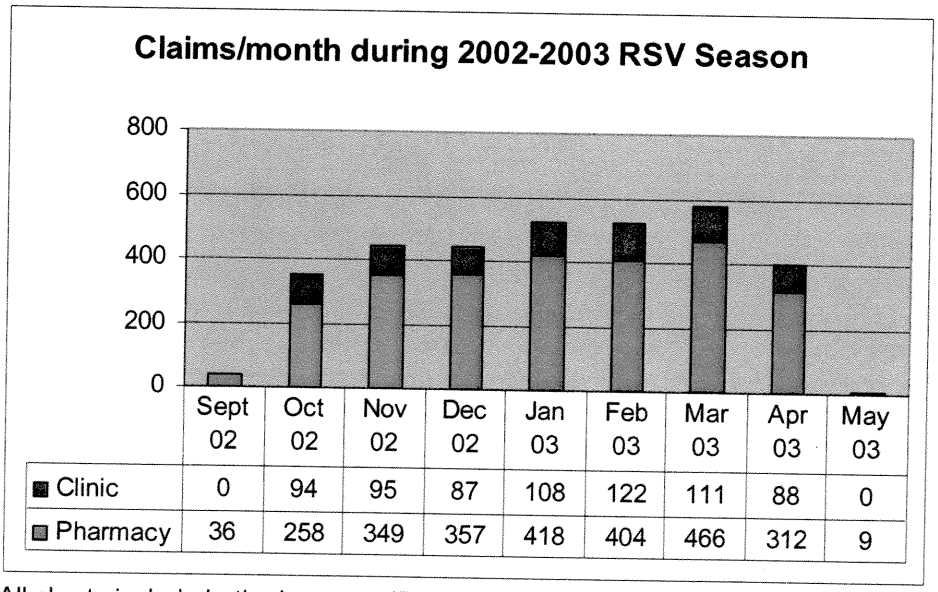
Drug Name	# of Claims	Total Units	Total $	Total Clients*	$/unit	$/Client	$/Claim
Synagis (pharmacy)**	2609	3369	$2,839,860.70	554	$842.94	$5,126	$1,088
Synagis (Clinic)	705	1785	$1,048,572.45	188	$587.35	$5,578	$1,487
Totals**	3314	5154	$3,888,433.15	742	$754.59	$5,223	$1,173

*14 clients received Synagis in both settings. ** Totals include both 50 mg and 100 mg vials.
Clinic claims billed in 50 mg increments.









	Sept 02	Oct 02	Nov 02	Dec 02	Jan 03	Feb 03	Mar 03	Apr 03	May 03
Clinic	0	94	95	87	108	122	111	88	0
Pharmacy	36	258	349	357	418	404	466	312	9

*All charts include both pharmacy (Rx) and physician office (OP) claims/clients

- **Prior Authorization requirements in other states**

Criteria	State
AAP Guidelines used	Alabama, Arkansas, Colorado, Delaware, Idaho, Indiana, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, North Dakota, South Carolina, South Dakota, Texas, West Virginia
Date Restriction	Alabama (3/31), Delaware (10/15-4/15), Indiana, (10/15-4/30), Maryland (10/15-4/15), Nebraska (3/31), New York (11/1), North Dakota (10/1-4/30), West Virginia (10/15-4/30)
Number of Doses	Alabama (6), Delaware (6), Idaho (5), Indiana (6), Maine (6), Maryland (5), New Jersey (6), North Carolina (5), South Carolina (7), West Virginia (6)
Number of units by weight	Arkansas, Maryland
Single season (except w/ CLD)	Idaho, Michigan
Provider restriction	South Carolina, Indiana – physician, hospital, or infusion center only
Age (other than per AAP guidelines)	Washington – (1 yr)

- **Recommendations**
- Current system: Use of Synagis for clients age 4 years or older requires prior authorization. Provides coverage for the children who are 2 years old at the beginning of RSV season, but who have a birthday during the season and are 3 years old at the end of the season.
- Possible Options:
    - Prior authorization using AAP guidelines
        - Prior authorization form
        - Weight based dosing to determine vials needed
    - Limit to 5 doses per season (based on AAP recommendations)
    - Limit to RSV season in first year of life, unless CLD criteria is met.
    - Require PA for children over 1 year of age
    - Restrict use to October through March or April
        - October 15 to March 31
        - October 15 to April 15

APPENDIX H

U.S. Infant Mortality Rate Rises for First Time Since 1958, CDC Report Finds

The infant mortality rate in the United States rose for the first time in more than 40 years between 2001 and 2002, according to a report released on Wednesday by the CDC's National Center for Health Statistics, the *Washington Times* reports. According to the report, titled "Deaths: Preliminary Data for 2002," the U.S. infant mortality rate increased from 6.8 deaths per 1,000 live births in 2001 to seven deaths per 1,000 live births in 2002, the most recent year for which data are available (Howard Price, *Washington Times*, 2/12). The data were collected from annual birth records and 96% of state death certificates from 2002, the *New York Times* reports (O'Connor, *New York Times*, 2/12). Although the United States "long" has had one of the highest infant mortality rates among developed countries, the rate has either declined or remained steady every year since 1958, according to the *Washington Post*. As a result, the 3% increase in the infant mortality rate between 2001 and 2002 surprised government scientists, the *Post* reports (Stein, *Washington Post*, 2/12). However, according to the CDC, the increase may be a "one-time blip," as preliminary data for 2003 indicate that the infant mortality rate declined between 2002 and 2003 (Yee, *AP/Chicago Tribune*, 2/12).

Pregnancy-Related Deaths

When researchers analyzed the data in a follow-up analysis, they determined that the increased rate was due to a rise in the number of deaths during the first week of life among low-birthweight infants, infants born with birth defects and infants born to women who had complications during pregnancy (Stein, *Washington Post*, 2/12). "It's very clear that these appear to be all pregnancy-related, as opposed to later deaths caused by external causes, like sudden infant death syndrome," Joyce Martin, a statistician at NCHS, said (*New York Times*, 2/12). Experts say that the increase in deaths among infants in the first week of life may be a result of a combination of factors, including an increase in the number of births among older women, an increase in the number of women who use of fertility treatments and advancements in addressing pregnancy complications, according to the *Post*. Older women are at an increased risk of pregnancy complications and their infants are more likely to be born with birth defects or a low birthweight (*Washington Post*, 2/12). In addition, a rise in use of fertility treatments led to a 400% increase between 1980 and 1998 in the number of multiple births in the United States, according to data released by the CDC in December 2003 (Maugh, *Los Angeles Times*, 2/12). Infants who are born as a result of a multiple-fetus pregnancy also are more likely to born preterm, with low birthweights and born to women who experience complications during pregnancy. However, Jun Zhang of the National Institute of Child Health and Human Development said that the "more important influence" on infant mortality is medical technology that allows doctors to determine problems in a fetus before birth and keep premature, sick infants alive after birth. Although these interventions increase the likelihood that an infant will survive delivery, the number of infants who die shortly after birth may increase as a result. "So it's a shift from fetal death to early neonatal death," Zhang said (*Washington Post*, 2/12).

U.S. Life Expectancy Reaches New High

The report also found that U.S. life expectancy in 2002 increased to a record high of 77.4 years (*Los Angeles Times*, 2/12). According to the report, based on data from more then 96% of state death certificates, life expectancy in 2002 increased for both men and women and for both whites and African Americans. In addition, the report found that age-adjusted mortality rates for the U.S. population decreased from 855 deaths per 100,000 residents in 2001 to 847 deaths per 100,000 residents in 2002. The only groups that did not experience a decrease in mortality rates were male and female American Indians and non-Hispanic white females, whose death rates were the same in 2001 and 2002 (CDC release, 2/11). The report found that mortality rates for most of the leading causes of death decreased in 2002 -- the mortality rate decreased by 3% for heart disease, by about 3% for stroke and by 1% for cancer (*Los Angeles Times*, 2/11). The preliminary age-adjusted mortality rate for HIV/AIDS, the fifth leading cause of death for residents ages 25 to 44, decreased 2% in 2002 (CDC release, 2/11). However, in 2002, the mortality rate increased by 5.8% for Alzheimer's disease, by 3.2% for influenza and pneumonia, by 2.9% for hypertension and by 2.6% for blood poisoning (*Los Angeles Times*, 2/11).

REDUCING PRESCRIPTION DRUG ABUSE

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. Emergency room visits associated with narcotic pain relievers have increased 163 percent since 1995.

The President's National Drug Control Strategy engages Federal, state, and local officials; the medical community; and businesses working in the area of Internet commerce to prevent and stop the illegal sale, diversion, and abuse of prescription pshychotherapeutic drugs.

The Strategy focuses on three core tactics for reducing prescription drug abuse:

- ☑ Business outreach and consumer protection
- ☑ Investigation and enforcement against the illegal sale and diversion of prescription drugs
- ☑ Education and training of physicians and consumers

☑ **Business Outreach and Consumer Protection:** The Food and Drug Administration (FDA) will work to ensure product labeling that clearly articulates conditions for the safe and effective use of controlled substances so that commercial advertising fully discloses safety issues associated with the drug's use. Specific examples include labeling that properly identifies patients for whom these products are appropriate and that recommends a "stepped care" approach to the treatment of chronic pain, in accordance with treatment guidelines.

- ➢ FDA will consider Risk Management Programs (RiskMAPs) during the approval process for Schedule II opiate drug products. RiskMAPs help ensure the safe prescription and use of these drugs through identification of appropriate patients and monitoring for adverse outcomes.
- ➢ FDA, the Drug Enforcement Administration (DEA), and the White House Office of National Drug Control Policy will work with physician organizations to encourage comprehensive patient assessment prior to prescription of opiate therapy. Identification of persons at risk for opiate abuse and addiction will help their medical caretakers to more effectively monitor for signs of abuse.
- ➢ Federal agencies are enlisting the support of responsible businesses affiliated with online commercial transactions. Such businesses include credit card companies, shippers, and Internet Service Providers (ISP). These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities, while ISP and credit card companies will be requested to require Internet pharmacies to display on their websites the physical street address of their primary business locations.

☑ **Investigation and Enforcement:** The Internet is one of the most popular sources of diverted prescription drugs. An increasing number of rogue pharmacies – or "pill mills" – offer controlled substances and other prescriptions direct to consumers online. These unscrupulous entities are often foreign-based and undermine state licensing systems, exposing consumers to potentially counterfeit, adulterated, and contaminated products.

- ➢ The FDA's Office of Criminal Investigations (OCI) and DEA work together on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances.

Investigation and Enforcement (continued):

- DEA will deploy sophisticated web crawler/data mining technology to generate investigative leads that could lead to enforcement actions against illegal pill mills.
- ONDCP and DEA will work with state officials to expand the number of Prescription Monitoring Programs (PMPs) and to facilitate information sharing among jurisdictions. Currently, 20 states have PMPs to identify individuals who attempt to fill multiple prescriptions from numerous doctors ("doctor shopping"). This information can help reputable physicians and pharmacies prevent illegal diversion of controlled substances.
- FDA and U.S. Customs and Border Protection (CBP), with assistance from DEA, continue to do spot examinations of mail and courier shipments for foreign drugs to U.S. consumers to help FDA and CBP target, identify, and stop illegal and potentially unsafe drugs from entering the U.S. from foreign countries via mail and common carriers.

☑ **Education and Training:** One potential means of preventing diversion and abuse of prescription drugs is wider dissemination of continuing medical education programs for physicians and other health professionals regarding pain management. These programs will seek to balance the legitimate needs of patients against the risk of diversion and abuse.

- The DEA, with support from the FDA, is working to consult with medical associations to identify existing best practices in physician training in the field of pain management. The agencies plan to develop a mechanism to support the wider dissemination and completion of approved Continuing Medical Education (CME) courses for physicians who prescribe controlled substances. The curriculum will educate doctors on the appropriate medical use of opioids as well as the risks of abuse and addiction.
- ONDCP, DEA, and FDA will develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making direct purchases of controlled substances online. Currently, FDA, along with its sister agency, the Substance Abuse and Mental Health Services Administration (SAMHSA), have jointly developed a public service announcement campaign to better educate consumers on the abuse of prescription pain killers.

☑ **Protecting Safe and Effective Use of Medications:** Some estimate that more than 10 million Americans suffer from chronic pain. The efforts outlined in the National Drug Control Strategy to prevent and reduce the diversion and abuse of prescription drugs will help to ensure that patients have full and appropriate access to the medications that best meet their needs and that their healthcare providers are informed and trained to effectively manage pain while limiting potential for misuse, abuse, and addiction.

Prescription Abuse Targeted

By Jerry Seper
THE WASHINGTON TIMES
Published March 2, 2004

The Bush administration, for the first time, is planning a coordinated drug strategy targeting the illegal diversion and abuse of prescription drugs -- mainly pain relievers, sedatives and stimulants -- that has erupted nationwide in the past decade.

"The nonmedical use of prescription drugs has become an increasingly widespread and serious problem in this country, one that calls for immediate action," said John Walters, who heads the White House Office of National Drug Control Policy, upon announcing the new program yesterday.

"The federal government is embarking on a comprehensive effort to ensure that potentially addictive medications are dispensed and used safely and effectively."

Mr. Walters said recent data shows that prescription-drug abuse has increased at an "alarming rate" in the past 10 years; that nonmedical use of narcotic pain relievers, tranquilizers, stimulants and sedatives ranked second only behind marijuana as a category of illicit drug abuse among adults and youth; and that 6.2 million Americans abused prescription drugs during 2002.

He also said 13.7 percent of youths ages 12 to 17 abused prescription drugs at least once in their lifetimes and that emergency-room visits resulting from abuse of narcotic pain relievers had increased 163 percent since 1995.

More than 10 million Americans suffer from chronic pain, and the new White House strategy seeks to balance the need for effective pain-management therapies with the prevention of misuse, abuse and diversion of drugs such as Oxycontin and Vicodin.

Mr. Walters was joined by Food and Drug Administration Commissioner Mark McClellan, Drug Enforcement Administration (DEA) head Karen Tandy, Surgeon General Dr. Richard Carmona and Rep. Thomas M. Davis III, Virginia Republican and chairman of the House Government Reform Committee.

The new strategy incorporates education of medical professionals and consumers and outreach to businesses involved in Internet commerce, pharmaceutical manufacturers and pharmacies, as well as increased investigation and enforcement activities by the DEA aimed at the illegal sale, use or diversion of controlled substances, including those occurring over the Internet.

"Criminals who divert legal drugs into the illegal market are no different from a cocaine or heroin dealer peddling poisons on the street corner," Mrs. Tandy said. "DEA is aggressively working to put an end to this illicit practice, whether it occurs in doctors' offices or cyberspace, and ensure the integrity of our medical system."

Congress also is working to address prescription-drug diversion, said Mr. Davis, who said he was "particularly pleased" that the new strategy addresses the issue of prescription-drug abuse. He said he will introduce legislation soon to address the illegal and potentially deadly sale of prescription drugs over the Internet.

"The Internet creates an easy environment for illegitimate pharmacy sites to bypass traditional regulations and established safeguards. My legislation addresses these issues and makes it difficult for unlawful prescribing to occur," he said.

President Bush's 2005 budget requests $138 million for diversion-control programs. The Office of National Drug Control Policy seeks to reduce illegal drug use by 10 percent in two years and by 25 percent in five years through what Mr. Walters called "a balanced and comprehensive approach of stopping drug use before it starts, healing America's drug users and disrupting the market for illegal drugs."

Oklahoma Governor Pushes for Tobacco Tax To Provide Health Coverage to the Uninsured

Oklahoma Gov. Brad Henry (D) on Monday held a news conference to gather support for a net 52-cent tobacco tax increase that would help pay for health coverage for as many as 200,000 uninsured Oklahomans, the *Daily Oklahoman* reports. The 52-cent tax, which must be approved by voters in November and would raise about $130 million per year, also would fund a cancer research center and improve the state's trauma care system (Perez Snyder, *Daily Oklahoman*, 2/10). "The rising cost of health care is a significant challenge for every state in the nation," Henry said, adding, "The difference between the majority of states and Oklahoma is they have taken bold action to address their problems and we haven't. We should give Oklahoma voters the opportunity to decide whether they want to improve their health care system and cut youth smoking in the process" (Henry release, 2/9). Doctors and health officials support the plan, the *Oklahoman* reports. The *Oklahoman* does not provide any details on how the governor would use revenue from the tobacco tax increase to provide health insurance to the uninsured (*Daily Oklahoman*, 2/10).