

BRIEFING PAPER

October 24, 2007

Reissued November 14, 2007

**Effectiveness of Prometa Treatment Protocol  
in Pierce County Drug Courts**

Study Conducted for

Pierce County Performance Audit Committee

by

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# Pierce County

## Performance Audits

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October 24, 2007

To: Performance Audit Committee

From: Matt Temmel, Performance Audit Coordinator

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Re: Effectiveness of Prometa Treatment Protocol

The Prometa protocol, a proprietary plan to help treat drug addiction, has been used in Pierce County on a pilot basis since 2006. Public funding for Prometa became available in 2007 in the county and state budgets. This report originated out of a request to consider whether the Performance Audit Committee should undertake a special study of Prometa's effectiveness. To answer that question, performance audit staff addressed the following:

- Analyzed the evidence of Prometa's success.
- Assessed the risk to Pierce County by use of an unproved treatment protocol.
- Identified other jurisdictions that use Prometa in drug courts.
- Reviewed the plan for the upcoming evaluation by the University of Washington on Prometa effectiveness in the family drug court.
- Assessed whether Prometa is an effective use of Pierce County tax dollars.

The report includes materials from Hythiam, Inc., which markets and sells the Prometa protocol, and from Pierce County Alliance, the local drug treatment provider and a Hythiam licensee.

The report presents new data on the success of the 2006 Prometa pilot project in Pierce County, including drug court graduation rates, drug test results for Prometa clients, and cravings data reported by Prometa clients. In general, the report finds that the 2006 Prometa pilot project was not exceptionally successful.

The general conclusion is that a performance audit may not be appropriate, because definitive information on Prometa effectiveness will not be available until 2008 or 2009 through double-blind clinical studies. However, the report may be useful when deciding whether Pierce County should continue to provide funding for the Prometa protocol.

The suggestion to conduct a performance audit on Prometa issues was made in mid-September 2007, and work had to be conducted and completed prior to the County Council's deliberations on the 2008 budget. Only five weeks was available for the study.

William Vetter, Research Analyst, collected the information found in the report on pilot projects, clinical studies, scientific papers, and client data from the 2006 pilot project, under the supervision of Matt Temmel. Writing of the report was a team effort.

The study was conducted in accordance with "Yellow Book" standards for performance audits, with the exception that the Pierce County Alliance did not receive a draft report for review and comment. As noted above, the project timeline was very short. However, an exit interview was conducted with Alliance staff to discuss the study findings, and appropriate revisions were made to the report as a result.

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## Postscript

November 14, 2007

After the briefing paper was published on October 24, Pierce County performance audit staff conducted a thorough review of the report documentation and spreadsheets on which the report was based. No significant errors were found that impact the report's conclusions.

Performance audit staff met on November 7 with staff of the Pierce County Alliance to review the data in detail and try to resolve the discrepancies with the Alliance's data. The meeting resulted in a partial resolution of the data differences, as reported below in Appendix 6.

The briefing paper is now reissued and presented to a budget session of the Pierce County Council on November 14, 2007. The text (pp. 1-20) is the same as the October 24 report, except to add the material on this page and the next, correct previous typographical errors, and insert pointers to new material that appears in the appendices.

Appendices 1 – 3 (pp. 22-31) are the same as presented on October 24. However, Appendix 4 (starting at p. 32) was mislabeled in the October 24 report; it was not an Alliance presentation to a committee of the Pierce County Council in February 2007 but was an earlier presentation that reported the pilot project results after six months. In this report, we have substituted as Appendix 4 the Alliance material actually presented to the Public Safety and Human Services Committee of the Council on February 27, 2007 reporting the pilot project results after ten months.

The material of most interest in this report starts at page 51 and is as follows:

- Appendix 5 is a "Postscript" memo from performance audit staff updating the data and commenting on key issues.

- Appendix 6 is a press release by Hythiam, Inc., November 1, 2007, announcing the results of a double-blind study by Dr. Harold Urschel III, M.D.
- Appendix 7 is a press release by the Pierce County Alliance, October 31, 2007, responding to what the Alliance calls inaccuracies in the October 24 briefing paper.
- Appendix 8 is a letter from staff of the Pierce County Alliance, correcting the Alliance's press release of October 31.

As we were going to press with this reissue (on November 13, 2007), the Alliance was preparing materials for the budget session on November 14. We look forward to receiving the materials later today and being able to comment on them at the meeting tomorrow.

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## I. BACKGROUND

At the request of the Performance Audit Committee, staff conducted a brief planning study to analyze whether effectiveness of the Prometa protocol to treat drug court clients is an appropriate topic for a performance audit. The study was conducted over the five weeks between September 14 and October 19, 2007.

The main objectives were to (a) collect basic information about drug courts, Prometa, and related topics; and (b) recommend whether the Performance Audit Committee should undertake a special study of the effectiveness of the Prometa treatment protocol.

Specifically, the aim was to gather information and assess the following:

1. Analyze evidence of Prometa's success, including whether the available evidence meets industry standards.
2. Assess the risk to Pierce County as a result of being mentioned in Prometa advertising, including whether there is additional risk because the treatment may be research on human subjects.
3. Identify other jurisdictions that use Prometa and analyze their success rates.
4. Review the planned University of Washington study on Prometa effectiveness, including scope, research design, and status of the evaluation.
5. Assess whether Prometa is an effective use of county tax dollars.

### A. Prometa Treatment Protocol

The Prometa protocol is a treatment plan offered by Hythiam, Inc., a publicly-traded company located in Santa Monica, California. The protocol is an add-on to traditional, psychosocial treatment for drug addiction. It includes five in-office medical treatments (infusions) over a three-week period, one month of at-home prescription medications, nutritional support and education, and initial psychosocial counseling. The drugs are:

- Flumazenil (developed to counteract sedatives)
- Hydroxyzine (an antihistamine, taken as pills)
- Gabapentin (an anticonvulsive, taken as pills)

Hythiam, Inc. does not produce or distribute the drugs used in the protocol. Each drug has been FDA-approved for treatment of other conditions (not drug addiction) but is used "off label" to address disorders for which they were not originally developed or approved. Hythiam licenses treatment providers to sell the protocol and also contracts with physicians to deliver the drugs to patients.

According to Hythiam, the drugs in the Prometa protocol correct chemical imbalances in the brain related to cravings and inhibitions. In theory, patients using the protocol are better able to address their addiction because Prometa has eliminated the cravings for drugs.

Hythiam's 2006 Annual Report states that Prometa is used at 64 private treatment clinics nationwide and in four criminal justice systems (including Pierce County).

Other basic information about Prometa appears in Appendix 1, 2, 3, and 4 of this report:

- ❑ **Appendix 1** is a promotional brochure, "Hythiam and the Criminal Justice System." The brochure describes the Prometa protocol, discusses how substance dependence is a brain disease that deserves medical treatment, and presents results of two Prometa pilot programs (Pierce County and Gary, Indiana).
- ❑ **Appendix 2** is a one-page excerpt from Hythiam's 2006 annual report on the pilot projects in Pierce County and Gary, Indiana as well as Collins County, Texas.
- ❑ **Appendix 3** is a news release by Pierce County Alliance announcing the results of Prometa treatment after 14 months (May 21, 2007).
- ❑ **Appendix 4** is a presentation by Pierce County Alliance to a committee of the Pierce County Council on February 27, 2007 about the Results of the 2006 Prometa Pilot Project.

## **B. Pierce County Drug Courts**

Since 1994, the Pierce County drug court program has diverted persons charged with felony offenses from prosecution into a drug treatment program. In 2001, a federal grant enabled Pierce County to start a family drug court for drug-related state dependency cases. Early research indicates that drug courts, including those in Pierce County, are effective in treating addiction, avoiding costs of incarceration, and reducing recidivism.

In the felony drug court, persons charged with certain low-level felonies can avoid jail time by stipulating to the charges and agreeing to abide by a court-monitored chemical dependency treatment plan. The treatment plan includes counseling and regular drug testing. If the judge finds that a drug court client has violated the terms of the treatment plan – for example, by testing positive for drug use – the person is subject to sanctions and termination from drug court. Termination from drug court includes conviction on the original charges and a jail sentence.

A Superior Court judge is assigned to the felony drug court, which is staffed by attorneys from the Department of Assigned Counsel and the Prosecutor's office.

The family drug court was designed to serve families "involved in drug-related state dependency cases by providing drug-addicted parents with an alternative to the potential

termination of parental rights.”<sup>1</sup> As in the felony drug court, clients face sanctions if they do not comply with the treatment plan.

A Superior Court judge is assigned to the family drug court, which is staffed by attorneys from the Pierce County Department of Assigned Counsel and the state Attorney General’s office. Pierce County deputy prosecutors do not work in family drug court.

To provide drug treatment services, Pierce County contracts with the Pierce County Alliance, a non-profit addiction treatment provider. Treatment includes an assessment, a treatment plan, group and individual counseling, regular drug testing, and psychosocial support in a three-phase program. The Alliance also provides assistance with childcare, housing, and transportation for drug court clients.

In 2006, the Alliance began offering the Prometa treatment protocol as an addition to its regular treatment program, at additional cost. The Alliance, without public funding, conducted a pilot project in which 40 clients were served between March and June 2006, with follow-up services in later months. Public funding became available in 2007 through both Pierce County and the State of Washington. **Exhibit 1** indicates the number of drug court clients served with Prometa each year.

Exhibit 1			
<b>Pierce County Alliance Prometa Clients (Drug Court)</b>			
<b>2006 Prometa Pilot Project</b>		<b>2007 Prometa Pilot Project</b>	
Treatment started March - June 2006		Treatment started April 2007	
	<i># Clients</i>		<i># Clients as of Oct. 3, 2007</i>
Felony Drug Court	24	Felony Drug Court	34
Family Drug Court	16	Family Drug Court	13
Total	40	Total	47
<i>Source: budgets and client lists from Pierce County Alliance</i>			

The Prometa population amounts to roughly 10% of the new admissions into felony drug court per year and 20% to 30% of admissions into family drug court.

In addition to the Prometa public clients shown above, the Pierce County Alliance has served approximately 50 private-pay Prometa clients since 2006.

<sup>1</sup> Pierce County Department of Assigned Counsel:  
<http://www.co.pierce.wa.us/pc/abtus/ourorg/dac/familydrugcourt.htm>

### C. Prometa Funding and Contract Arrangements

Exhibit 2 shows funding for Prometa by Pierce County and the State of Washington.

Exhibit 2

#### Public Funding of Prometa in Pierce County

Calendar Year 2007		Calendar Year 2008	
<i>Source</i>	<i>Amount</i>	<i>Source</i>	<i>Amount</i>
Pierce County	\$400,000	Pierce County	\$400,000
State	\$89,000	State	\$178,000
<b>Total</b>	<b>\$489,000</b>	<b>Total</b>	<b>\$578,000</b>

The \$400,000 per year in county funding is appropriated in the county budget to Pierce County Superior Court, and then contracted to the Alliance under a contract with Superior Court. According to the contract, the clients may be participants in either the felony or the family drug court (discussed later).

The state funding shown above in Exhibit 2 is based on an appropriation in the state budget [Chapter 522, Laws of 2007, section 208 (4)]. It provides \$250,000 in state fiscal year 2008 and \$250,000 in state fiscal year 2009 for the Department of Social and Health Services to contract for the following:

- a. A pilot program in Pierce County for family therapeutic court services that include chemical dependency treatment with use of the Prometa protocol; and
- b. An independent evaluator to evaluate the efficacy of treatment with the Prometa protocol as compared to other drug treatment and to no treatment.

Based on this direction in the state budget, the state biennial funding for Prometa will be allocated as follows:

1. Pierce County Alliance will receive \$178,000 each state fiscal year (July – June) for Prometa treatment of clients in the family drug court. This money flows by contract from DSHS to Pierce County Human Services and then to Pierce County Alliance. Exhibit 2 above converts this funding to a calendar year basis.
2. DSHS will contract with the University of Washington for an evaluation, with an approximate cost of \$105,000. (The evaluation is discussed later in this briefing.)

Billing under each contract (Superior Court and Human Services) is at the rate of \$5,000 per client treated with Prometa. At this funding level, the combined state and county

funding is sufficient to support Prometa treatment for approximately 97 clients in 2007 and 115 clients in 2008.<sup>2</sup>

So far this year, Pierce County Alliance has billed Superior Court \$225,000 for the 45 Prometa clients served through September 30, 2007. (As of this writing, October 22, five other clients have been started on Prometa since October 1, bringing the 2007 total to 50 clients served to date.)

The two contracts for Prometa services have some overlap:

- Under the contract with Superior Court, the funding is for treatment with the Prometa protocol in either the felony or the family drug court.
- The Human Services contract (state funding) is limited to clients treated with Prometa who are in the family drug court.

In 2007, the Alliance has not billed yet under the contract with Human Services (state funding) because the contract with Superior Court is sufficient to support the clients served to date in both courts.

In the future, according to the chief financial officer of the Pierce County Alliance, Superior Court will be billed for the Prometa clients in felony drug court, and Human Services will be billed for Prometa treatment in family dependency drug court.

#### **D. Contract between Hythiam and Pierce County Alliance**

Hythiam has granted a license to Pierce County Alliance to offer treatment with the Prometa protocol through a physician. The contract specifies the fees paid to Hythiam by the Alliance (\$2,500 per public-pay patient, \$7,425 per private pay for treatment of meth or cocaine addiction).

Under the contract, the Alliance is required to report Prometa client data to Hythiam, and Hythiam may create reports and promotional materials using that data. According to the contract, Hythiam controls the public information about Prometa. For example:

- “Hythiam, in its sole discretion, will determine the type, extent and content of the data collected and the reports prepared, if any, for each patient.” (Schedule A)
- Public information and clinical presentations provided by the Alliance must be consistent with reports and marketing materials provided by Hythiam. (section 6)
- The Alliance agrees to market and promote the Prometa protocol to area drug courts, other criminal justice programs, contracts with managed care companies, third-party payers, and the general public. (sections 5, 6, and 7)

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<sup>2</sup> The calculations are as follows:  $\$489,000 / \$5,000 = 97.8$  clients.  $\$578,000 / \$5,000 = 115.6$  clients.

## II. RESEARCH ON PROMETA EFFECTIVENESS

### A. “Off Label” and “Double Blind” Studies

Hythiam presents Prometa as a promising innovation in the treatment of stimulant addiction. The company maintains that Prometa has been exceptionally effective in early research in both voluntary and drug court treatment settings. Two clinical studies (discussed later) indicate that Prometa has reduced cravings for drugs in addicted patients. In addition, testimonials from treatment professionals and former drug court clients indicate that Prometa has been dramatically successful. They report that Prometa has allowed clients to be more accepting of treatment and more engaged in the drug court process.

Some professionals, on the other hand, believe that the claims of Prometa effectiveness are premature. Skeptics or critics raise two main concerns.

1. **The drugs in Prometa are used “off-label.”** The U.S. Food and Drug Administration approves drugs for use in treating certain conditions. Physicians routinely prescribe drugs for other conditions, which is called “off-label” use. The FDA also prohibits pharmaceutical companies from promoting drugs for off-label uses. However, because Hythiam markets and sells the “protocol” rather than the drugs in the protocol, they are exempt from such regulations.
2. **“Double-blind” clinical studies are in progress but have not been completed,** and thus Prometa is not an “evidence-based” treatment.

The clinical studies conducted on Prometa thus far have been “open-label” studies. Open-label studies are generally considered preliminary research, while double-blind studies are the “gold-standard” of evidence-based treatments.

In open-label studies, patients are aware they are receiving the drug, and the study results thus may be influenced by patient expectations.

Double-blind, or “placebo-controlled,” studies are designed to test whether a drug provides a benefit over and above what a patient might experience without the drug. These studies are set up so that neither the patient nor the physician knows whether the patient is receiving the drug or a “placebo” (an inactive compound such as sugar water).

The “placebo effect” refers to the fact that many drugs have been beneficial not because of the drugs or procedures themselves, but because **the patient expects the treatment to provide a benefit and actually does improve.**

There is a vast literature on the placebo effect. According to a New York Times article, “the placebo effect is so huge – between 35 and 75 percent of patients taking dummy pills in studies of new drugs – that it should probably be put to use in clinical practice.”<sup>3</sup>

For a drug addiction treatment to be approved by the National Institute on Drug Abuse, the treatment must demonstrate effectiveness in two double-blind studies before NIDA approval. In addition, the Substance Abuse and Mental Health Services Administration (SAMHSA) lists double-blind studies as the highest level of evidence in classifying treatments as “evidence-based.”

While NIDA and SAMHSA approval is not legally required for any treatment, it is often required in practice. For example, the contract between Pierce County Superior Court and the Pierce County Alliance for treatment of felony drug court clients requires the Alliance to use treatments approved for use by NIDA and SAMSHSA. This provision does not appear in the Superior Court contract for Prometa treatment.

## **B. Prometa Clinical Studies**

Studies on the drugs used in Prometa have yielded conflicting results. One study conducted in 2006 showed that flumazenil (a drug included in Prometa) increases levels of GABA – a brain chemical responsible for inhibition – in methamphetamine-addicted rats.<sup>4</sup> Another study indicated that gabapentin (another drug used in Prometa) was not effective in treating methamphetamine addiction.<sup>5</sup>

Hythiam has funded several clinical studies assessing the effectiveness of the Prometa protocol in treating addiction. Exhibit 3 lists the current studies on Prometa.

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<sup>3</sup> Margaret Talbot, “The Placebo Prescription,” New York Times, January 9, 2000, available at <http://www.nytimes.com/library/magazine/home/200000109mag-talbot7.html>

<sup>4</sup> Smith, Kemelman, & Carpov, Chronic Methamphetamine Administration Increases GABA 4 Expression in Hippocampus and Cortex: Reversal by Flumazenil Treatment. Study funded in 2006 by an unrestricted grant by Hythiam.

<sup>5</sup> Heinslerling, Shoptaw, Peck, Yang, Liu, Roll, & Ling (2006). Randomized, placebo-controlled trial of baclofen and gabapentin for the treatment of methamphetamine dependence. *Drug and Alcohol Dependence*, 85(3), pp. 177-184.

Exhibit 3

**Clinical Studies on Prometa**

	<b>Researcher</b>	<b>Study Type</b>	<b>Results Available to Public</b>
1	Dr. Harold Urschel, Research Across America, Dallas, Texas	Open-label, 50 participants	Available
2	Dr. Jeffrey Wilkins, Cedars-Sinai Medical Center	Open-label, 30 participants	Available
3	Dr. Walter Ling, UCLA Integrated Substance Abuse Program	Double-blind, 90 participants	Mid – 2008, or later
4	Dr. Harold Urschel, Research Across America, Dallas, Texas	Double-blind, 84 participants	Mid – 2008, or later
5	Dr. Jeffrey Wilkins, Cedars-Sinai Medical Center	Double-blind, 80 participants	Unknown
6	Dr. Raymond Anton, University of South Carolina, Charleston Alcohol Research Center	Double-blind, 60 participants	Unknown
7	Dr. Jenny Starosta, Institute of Addiction Medicine, PA	Double-blind, 60 participants	Unknown

The open-label study conducted by Dr. Harold Urschel, a Hythiam licensee (#1 in the previous exhibit) was recently published in the *Mayo Clinic Proceedings*.<sup>6</sup> The study results suggest that Prometa is effective in reducing cravings for people addicted to methamphetamine. Dr. Jeffrey Wilkins’ open-label study (#2 above) suggests that Prometa is effective in treating alcohol addiction.

Most researchers give less weight to open-label studies because they do not include a control group. In general, double-blind studies are more reliable, and the results of those studies will not be known until 2008 or later. [For the results of the double-blind study by Dr. Harold Urschel (#4 above), see Appendix 5, “Postscript” presented to the Pierce County Council on November 14, 2007.]

**C. Prometa Pilot Projects**

Chemical dependency treatment within drug courts has been very effective compared with traditional treatment in other settings. One reason for this success is that treatment in drug courts has a coercive aspect that may influence behavior. Clients face sanctions such as

<sup>6</sup> <http://www.mayoclinicproceedings.com/pdf/8210/8210a2.pdf>

jail time, prosecution, and the loss of children as a result of noncompliance with treatment. In traditional settings, the clients are treated voluntarily. Thus, when comparing treatment outcomes, it is important to distinguish drug court from voluntary treatment settings.

Hythiam has reported that several drug courts have adopted or are in the process of adopting Prometa as a treatment for chemical dependency. Exhibit 4 lists those courts in two ways: (a) how Prometa was implemented in those courts, as reported by Hythiam; and (b) the current status of Prometa, as found in our recent interviews with project personnel.

Exhibit 4

**Status of Prometa Pilot Projects in Drug Courts**

<b>Jurisdiction</b>	<b>Hythiam Description</b>	<b>Current Status: Audit Findings</b>
Pierce County	2006: 40-patient pilot program with very successful results	2006 results are discussed later in this report. 2007 Prometa project includes 50 clients as of 10/22/2007.
Fulton County, Georgia (Atlanta)	2007: 4-patient pilot	Pilot was canceled due to physician misconduct. Another pilot is possible pending results of other pilot projects or clinical studies.
Idaho Drug Courts	2006: 30-patient pilot program in Idaho Falls, Idaho	There was no pilot program. The Idaho Drug Court Coordinating Committee voted not to work with Hythiam pending results of double-blind studies. Drug court administrator expressed concern that Hythiam has used Idaho in promotional materials.
Gary, Indiana	2006: 20-person pilot program; Prometa was adopted due to overwhelming success of pilot.	Pilot project ended early, and Prometa was not adopted as an ongoing part of drug treatment.
Las Vegas, Nevada	2007: 20-patient pilot program announced September 2007	Unknown
Collin County, Texas	2006: 20-person pilot program	Unknown

Source: Hythiam website, Hythiam 2006 annual report, promotional materials received from Pierce County Alliance, and performance audit staff telephone interviews.

## **D. University of Washington Evaluation**

Based on the proviso in the current state budget, Dr. Dennis Donovan, head of the Alcohol and Drug Abuse Institute at the University of Washington, will conduct an evaluation of the Prometa protocol in the Pierce County family dependency drug court and the Pierce County Alliance treatment program.

The evaluation is designed to determine whether family drug court clients using Prometa receive a benefit “over and above” what they would receive from regular treatment. Outcomes for clients served with Prometa will be compared with outcomes for a matched sample of other family drug court clients who received regular treatment.

The evaluation will examine data from the “TARGET” data that drug treatment providers are required to report on a regular basis to the DSHS Division of Alcohol and Substance Abuse. The data will include measures such as the following:

- Treatment retention
- Treatment completion
- Family reunification
- Criminal behavior
- Further treatment
- Further dependency filings

The evaluation prospectus identifies several challenges that the UW researchers will face. First, they must define and identify a group of non-Prometa clients for comparison with Prometa clients based on certain characteristics.

Another (and more difficult) problem is that the evaluation should take into account possible “selection bias” – that is, the possibility that the clients who chose to undergo the Prometa protocol had a greater personal motivation to beat their addiction and thus are self-selected for success. Selection bias is a very difficult problem in all evaluations that do not include random assignment to a control group with use of a placebo.

The UW evaluation is designed to provide the most useful information possible in the circumstances, in our opinion, but it will have two limitations that are relevant to the questions addressed in this report.

1. The UW evaluation will address Prometa outcomes for clients of the family drug court. The felony drug court will not be studied.
2. The UW final report will not be ready until 2009, possibly as late as June 2009.

## E. Risk to Pierce County

The Performance Audit Committee asked staff to investigate whether the prominence of Pierce County in Hythiam marketing materials increases Pierce County's liability. It is true that the Pierce County pilot project is featured extensively on the Hythiam website and in printed marketing materials. It is also true that the efficacy of the Prometa protocol has not been demonstrated in double-blind studies. However, it is unclear whether this increases the county's risk. Here are some matters to be considered.

1. Pilot project clients treated with the Prometa protocol are required to sign a four-page waiver declaring that they or their spouse, families, or heirs will not sue Pierce County.
2. The Pierce County Risk Management Office, after reviewing the waiver and the Prometa contract between Superior Court and the Alliance, found that the contract presents an acceptable level of risk.
3. Hythiam manages risk through an exhaustive list of disclaimers, such as the following provisions in the contract with Pierce County Alliance.
  - ❑ Under Section 10.4, the Alliance and each authorized physician shall maintain professional liability insurance (\$1 million per occurrence and \$3 million per annual aggregate) and general liability insurance (\$1 million per occurrence and \$5 million per annual aggregate). Hythiam agrees to maintain Errors and Omission insurance (\$1 million per occurrence, \$5 million total) and general liability insurance (same limits).
  - ❑ Under Section 13, Disclaimer of Warranties, Alliance agrees that the Hythiam services do not provide a warranty of any kind. Hythiam makes no warranties about fitness for a particular purpose, data accuracy, etc. Hythiam also makes no representations, expressed or implied, about the safety or efficacy of the licensed technology.
  - ❑ Under Section 14, Limitation of Liability, Hythiam assumes no responsibility for how the Alliance or authorized physicians use the licensed technology, or for injury to persons or property. Alliance agrees that in no event will the total aggregate liability of Hythiam for any claims, losses, or damages exceed \$10,000.

A related question is whether the use of the Prometa protocol in Pierce County prior to completion of proper testing amounts to research on human subjects and thus should have approval by a human subjects institutional review board. According to staff of the state DSHS institutional review board, there is a fine line between "treatment" and "research." The upcoming UW evaluation (page 10) is "research" into client records and will require approval by a human subjects institutional review board. But the Prometa pilot project – because it is "treatment" – does not.

### **III. PROMETA IN PIERCE COUNTY DRUG COURTS**

#### **A. Measures of Success**

One challenge in measuring success in drug courts is identifying appropriate clients for comparison. The felony drug court and family drug court have different judges, attorneys, and clients, and thus outcomes may differ by court. Another problem is to find data relevant to drug court success and decide which measures are most appropriate. In the short time available for this study, we focused on the 2006 Prometa pilot project in Pierce County and developed data for three measures of success:

- Graduation rates for Prometa clients in the felony and family drug courts compared with historical graduation rates for Pierce County Alliance clients.
- Drug tests for Prometa clients versus reported results for other drug court populations and versus previously reported results for Prometa clients in Pierce County.
- Cravings data reported by Prometa clients. The Alliance collects cravings data only for Prometa clients, so comparisons with other populations are not possible.

To collect these data, Performance Audit staff reviewed the case files of all 40 drug court clients treated with Prometa in the 2006 pilot project. For the 2007 Prometa clients, more limited information was obtained. To provide context for the information, we reviewed a large amount of literature and conducted telephone interviews with drug court authorities in other jurisdictions and in other states.

The following data suggest that Prometa was not exceptionally successful in Pierce County. The results of the 2006 Prometa pilot program do not appear to exceed results normally found in other drug courts.

#### **B. Drug Court Graduation Rates**

Exhibit 5 shows the drug court graduation/termination rates for the clients served in the 2006 Pierce County Prometa pilot project compared with the general Pierce County drug court population.

Exhibit 5

**Drug Court Graduation Rates**  
**2006 Pierce County Prometa Pilot Project**

Clients	% Graduated	% Terminated
2006 Prometa Pilot Program Clients (n = 40)	<b>47%</b>	<b>53%</b>
All Pierce County Drug Court Clients, 2003-2006 *	<b>43%</b>	<b>57%</b>

\* Source: Prometa case files and DSHS "Target" data.

The above data indicate that the Prometa 2006 pilot project clients, in aggregate, had a slightly more favorable graduation rate than other Pierce County drug court clients.

The graduation data reveal a major difference between the two drug courts. As shown in the Exhibit 6 (next page), 68% of the Prometa clients from family drug court continued successfully in treatment and later graduated from the program. In the felony drug court, only 29% of the Prometa clients graduated.

These data must be interpreted with caution. Graduation does not necessarily indicate success. For example, one of the seven graduates from the felony drug court in the 2006 pilot project was recently re-arrested on new felony charges.

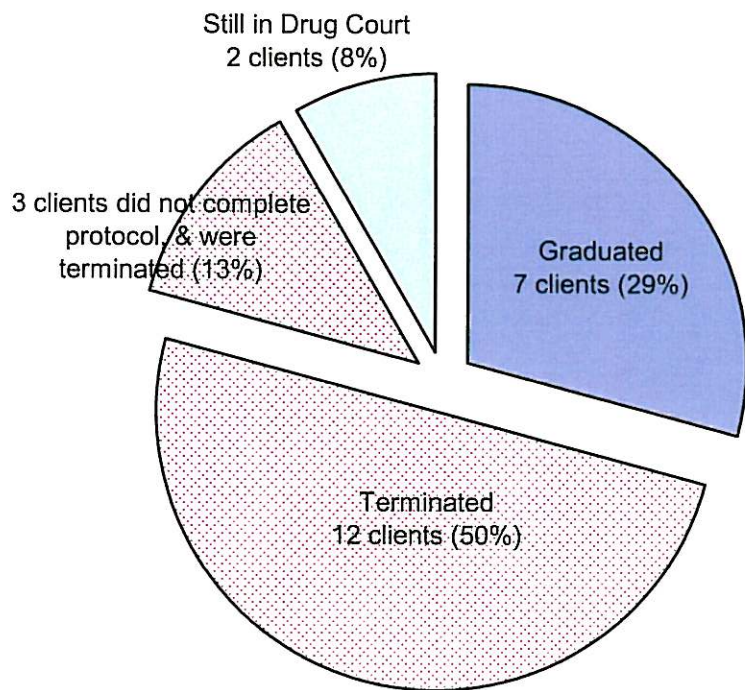
Another issue is whether graduation can be reasonably attributed to the Prometa intervention. For example, some of the eventual graduates were "clean and sober" with negative urinalyses for many months before starting the Prometa protocol. The case files also reveal a number of "confounding factors," such as intensive counseling and in-patient treatment, which may have played a role in the client's successful treatment. On the other hand, the Alliance suggests that the Prometa clients from felony drug court were more difficult than average felony drug court clients. We did not have an opportunity to analyze this issue through study of the client files.

Conversely, termination from drug court is perhaps not always an unfavorable outcome. According to the Alliance, two of the Prometa clients in felony drug court were voluntary terminations, and outcomes were good for these persons – e.g., one or two people obtained a good job and did not have time to continue in drug court.

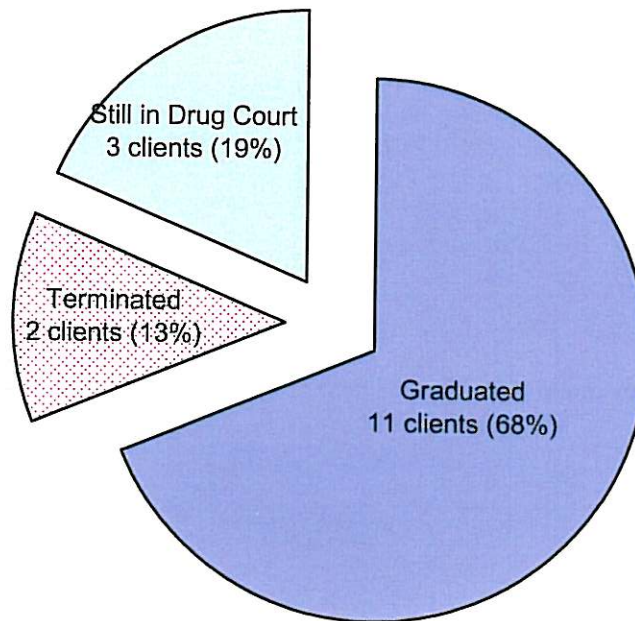
2006 Prometa Pilot Project (March - June 2006)

**Drug Court Status as of October 2007**

**FELONY DRUG COURT (n = 24)**



**FAMILY DRUG COURT (n = 16)**



### C. Urinalysis Test Results

Our review of the client contact logs from the 2006 pilot project included collecting data on urinalysis tests for all 40 clients. Exhibit 7 summarizes the data about how many clients remained drug-free after being treated with the Prometa protocol. Our results are different from the figures previously reported by Hythiam and the Alliance.

#### Exhibit 7

### Drug Use Follow-Up Results for 2006 Pilot Project

Source	Percentage of Clients Who Remained Drug Free	
	6 months after Prometa	14 months after Prometa
Reported results	<b>92%</b>	<b>86%</b>
Performance Audit analysis	<b>64%</b>	<b>50%</b>

The above data refer to the number of people who remained drug free 6 months and 14 months after the first Prometa infusion. [See Appendix 5, “Postscript” presented to the Pierce County Council on November 14, 2007.]

Another way of looking at the data is to examine the total number of urinalysis specimens and calculate the percentage of negative test results (i.e., the test revealed no drugs prohibited in the treatment program).

Hythiam and the Alliance have reported that Pierce County drug court clients in the 2006 pilot project tested negative for drugs on 98% of their urinalyses after starting Prometa. Our review of the client files found a somewhat different picture:

- 95% of the tests were negative if diluted samples and unexcused absences are excluded from the analysis.
- 87% of the tests were negative if diluted samples and unexcused absences are included.

Exhibit 8 shows these results along with reported urinalysis results from other drug courts. It appears that the data from the 2006 Prometa pilot project do not exceed the reported rates of negative urinalysis achieved in many other jurisdictions.

Exhibit 8

**Urinalysis Test Results**

Source	Percentage of negative drug tests
<b>2006 Prometa Pilot Program Clients</b>	
Hythiam-Reported Results	<b>98%</b>
Performance Audit Analysis	<b>87%</b>
<b>Performance Audit Drug Court Survey<sup>7</sup></b>	
Pierce County Alliance	80% - 85%
King County Drug Court Program	87%
Thurston County Drug Court Program	94%
Snohomish County Drug Court Program	94%
<b>National Studies<sup>8</sup></b>	
Office of National Drug Control Policy	84% - 98%
U.S. Office of Justice Prog. Drug Court Report	>90%
American University Drug Court Survey	90%
<b>Other Localities<sup>9</sup></b>	
New Jersey Adult Drug Courts	96%
Ada County (Boise), ID	98%
Durham, NC Family Dependency Drug Court	97%

Urinalysis results for drug courts locally and nationally are generally negative for drug use over 90% of the time, as shown above in Exhibit 8. For its general population, the Alliance indicates that 80 to 85% of the UA tests are negative. Specimens are random and given in controlled conditions, which could possibly explain why the Alliance numbers are lower than the figures reported by other jurisdictions. However, interviews with drug court staff in King, Snohomish, and Thurston counties also indicated that the testing is random and controlled in those programs.

<sup>7</sup> Performance Audit Staff interviews with drug court staff.

<sup>8</sup> “Drug Policy Information Clearinghouse Fact Sheet,” Office of National Drug Control Policy; “Looking at a Decade of Drug Courts,” U.S. Department of Justice; 1998 Drug Court Survey: Preliminary Findings. Washington, D.C.: Drug Court Clearinghouse and Technical Assistance Project, American University.

<sup>9</sup> New Jersey Administrative Office of the Courts, Drug Court Unit, Trenton, NJ, 2006; Performance Audit Staff interview with Ada County drug court staff; Durham Family Treatment Court Process Evaluation Report 2005, innovation Research & Training, Inc.

## D. Cravings

Cravings are important in the debate about Prometa. According to the Hythiam literature, the Prometa protocol has a major impact on drug addiction by eliminating or reducing the cravings for methamphetamine or cocaine. As previously mentioned, Dr. Walter Urschel found in an open label study that Prometa treatment had a significant impact in reducing cravings, as reported recently in the *Mayo Clinic Proceedings*.<sup>10</sup> During the course of this study, we heard anecdotes that Prometa helps many clients to overcome their cravings and become more amenable to psychosocial treatment. These observations make it especially important to analyze the cravings data collected for the Prometa clients.

During the 2006 pilot program, Pierce County Alliance staff asked each Prometa client to rate the intensity of his/her cravings for meth or cocaine on a scale of 1 to 10, with 10 being the strongest possible craving. Cravings ratings were recorded as “baseline data” for each client just prior to Prometa treatment and then once a week for the next 12 weeks.

Hythiam has reported that nearly all of the Pierce County drug court clients in the 2006 pilot project experienced a 100% reduction in cravings after using Prometa.

We examined the cravings data for all 40 clients in the 2006 pilot project. Exhibit 9 presents the results of the analysis.

In the felony drug court, the cravings ratings are IDENTICAL for the Prometa clients who later graduated and those later terminated from the program. The cravings data for family drug court, while not completely identical, are very similar for the graduates and those terminated. This finding calls into question the value of cravings data in predicting drug court success.

Comparisons of cravings with other Pierce County drug court clients are not possible because cravings data exist only for the Prometa clients.

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<sup>10</sup> <http://www.mayoclinicproceedings.com/pdf/8210/8210a2.pdf>

Exhibit 9

**2006 Prometa Pilot Project - Summary of "Cravings Data"**

*On a scale of 0 to 10, 0 is no desire to use, and 10 is the most intense desire to use meth/cocaine during the last week*

**FELONY DRUG COURT**

Drug Court Clients	Average of Baseline Data	Average of Post-Measures
Later Graduated (n = 7)	10	0
Later Terminated (n = 11)	10	0
Still active (n = 1)	10	0
Inadequate data for five other clients		

**FAMILY DRUG COURT**

Drug Court Clients	Average of Baseline Data	Average of Post-Measures
Later Graduated (n = 11)	9.5	0.2
Later Terminated (n = 2)	9.0	0
Clients still active (n = 3)	9.3	0

*Source: Pierce County Alliance, cravings data sheets for 2006 pilot project.*

## IV. CONCLUSIONS

While Hythiam claims that the Prometa protocol has been exceptionally successful, the foregoing analysis indicates that the results of the 2006 Pierce County pilot project do not surpass results normally found in drug court settings. Supporters of the Prometa protocol maintain, however, they have observed dramatic improvements in the Prometa population.

Only double-blind clinical trials can determine whether the patient improvement is a result of treatment or other factors, including the placebo effect. Five double-blind studies are currently underway, and some of the studies may be complete in 2008. However, the study results will not have gone through the full process of peer review, publication, and availability to the public until some later time.

In the meantime, Pierce County must decide two issues, whether to fund Prometa in the future and whether to conduct a special study through the Performance Audit Committee.

On the audit issue, we recognize that performance audit organizations may conduct special studies on difficult topics such as this one. However, in our opinion, a performance audit may not be useful for the following reasons:

- ❑ A good performance audit contractor is certain to conclude that definitive conclusions about Prometa effectiveness will not be possible until the double-blind studies have been completed and fully reported. Such a conclusion would not represent an advance over current knowledge.
- ❑ A performance audit would duplicate or overlap with the planned University of Washington evaluation of Prometa effectiveness in the context of the family drug court.
- ❑ The evidence reported in this briefing might support a performance audit on the effectiveness of Prometa in the felony drug court. However, on the other hand, the available evidence also suggests that Prometa may not be effective in the felony drug court.

We were asked to address in this report whether Prometa is an effective use of Pierce County tax dollars. Two answers are possible, depending on the point of view:

1. According to advocates, Prometa is a promising advance that should be pursued rather than awaiting definitive proof via double-blind studies. Intervention is needed now to offer Prometa in publicly-funded treatment programs in order to make headway against the devastating problems of meth and cocaine addiction.

2. It is premature to fund the Prometa protocol because double-blind study results are not available, and because Prometa's success in pilot projects has been greatly exaggerated in Hythiam marketing materials.

If the Council wishes to make budget changes, it is worth noting that the current funding will exceed what can be spent this year. The Alliance has billed Superior Court for 45 clients treated with Prometa through September 30, and another five clients have been served in October, bringing the total served to 50 as of October 22. The county and state funding would allow up to 97 clients to be served.

If funding is to continue, we believe it is important to clarify funding responsibility for drug treatment in the two courts. In the felony drug court, the Prosecuting Attorney represents the State of Washington. In the family drug court, which hears dependency cases, the Attorney General represents the State. Contract funding should be structured so that Pierce County funds treatment in the felony drug court and the State funds treatment in the family drug court.

The Pierce County funding, which flows by contract from Superior Court to the Pierce County Alliance, can be utilized for Prometa services in either drug court – felony or family. The state funding, which flows by contract from DSHS to Pierce County Human Services and then to the Alliance, can be used only for Prometa services in the family drug court. Thus the current contract arrangements maximize the financial obligation of the county.

It would be more appropriate, in our opinion, to limit the scope of services under the Pierce County contract to the felony drug court, leaving the state to fund Prometa activities in the family drug court.

However, there is also an issue as to whether Pierce County should continue to provide funding for Prometa treatment. As shown in this report, the known outcomes for the felony drug court defendants who were treated with Prometa in 2006 are much less favorable than previously reported.

**NOTE:** On October 23, 2007, the Pierce County Council voted to limit county funding for Prometa treatment in 2007 to the amounts legally obligated, pending the availability of scientific evidence to prove Prometa's effectiveness. In effect, the vote cut off county funding in 2007 for further Prometa clients from the felony drug court, unless the action is reversed by an Executive veto or subsequent Council action. The state funding for Prometa treatment in the family drug court is unaffected by this action.