

THE AVISA GROUP

PROJECT:	FORECAST THE NEAR TERM PROSPECTS FOR STATE AND FEDERAL REGULATION OF METHADONE
DATE:	Summer 2003
CLIENT:	A potential investor in private fee-for-service methadone programs
RESULTS:	<p>We provided a comprehensive assessment within 60 days of engagement of the risks of additional state and federal regulation of methadone. Among the key findings we highlighted for this client were the following:</p> <ul style="list-style-type: none"> ➤ No immediate changes in Federal regulation are apparent: <ul style="list-style-type: none"> ○ The historical periodicity of changes in Federal regulation of methadone has been 7-8 years. ○ The last major change in Federal regulation occurred in 2001, when Federal regulation changed from inspection model (FDA and DEA) to an accreditation model with inspection (CSAT and DEA). ○ Recent publicity about deaths due to methadone are seen in the relevant federal agencies as more associated with pain clinics than with opiod treatment programs. ➤ Market risks: <ul style="list-style-type: none"> ○ Oxycontin® abuse has been an significant contributor to demand for methadone treatment; Federal and state regulatory and enforcement responses to Oxycontin® diversion have potential to reduce rates of abuse of these drugs, although overall rate of abuse of prescription opiates may not be greatly affected. ○ Buprenorphine and OBOT initiatives provide potential for treatment of opiod abuse in much less regulated settings than methadone clinics; both trends remain slow moving. ➤ State regulatory risks: <ul style="list-style-type: none"> ○ None of the ten states queried have a current interest in significant increases in regulation of methadone. ○ Methadone is still a stigmatized medication that provokes fear in some. ○ A portion of the treatment and regulatory community as well as the public at large oppose opiate substitution treatment as therapy for addiction, regardless of which drug is used. ○ Availability of methadone is vulnerable to unpredictable legislative and regulatory restriction. ➤ Although no increase in regulatory restrictions to availability is apparent today, the risk of adverse events associated with methadone inspiring new state and federal restrictions is always present. ➤ Opportunities: <ul style="list-style-type: none"> ○ Increases in funding for public and community-based methadone treatment programs is unlikely; competition from free and low-fee programs will remain limited.
OUTCOME	Client proceeded with an acquisition