

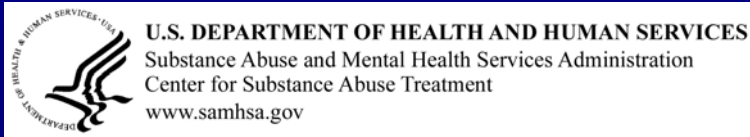
# SAMHSA/CSAT Evaluation of the Buprenorphine Waiver Program

## Expanding Treatment of Opioid Dependence: Initial Physician and Patient Experiences with the Adoption of Buprenorphine

American Society of Addiction Medicine  
May 5, 2006

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# Goals of this Presentation

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- Provide brief background on DATA and context for the related SAMHSA evaluation.
- Share highlights of FINAL results including:
  - Characteristics of patients treated under the Waiver Program and the doctors who treated them
  - Patients' receptivity to, satisfaction with and success under the Waiver program (6-month data)
  - Issues and challenges related to adoption of this new medication under the DATA Waiver Program
- Conclusions

# Background



# Drug Addiction Treatment Act of 2000 (DATA)

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- DATA establishes a program of waivers that permit qualified physicians to dispense or prescribe schedule III, IV, and V narcotic drugs or combinations of such drugs approved by the Food and Drug Administration (FDA) for the treatment of addiction to opioids.
- Buprenorphine (BUP) is the first medication to be eligible for use under the Waiver Program.
- DATA also specifies that the Secretary of the Department of Health and Human Services (HHS), in conjunction with the Attorney General, may make determinations concerning whether:
  - Treatments provided under the Waiver have been effective forms of maintenance and detoxification treatment in clinical settings;
  - The Waiver has significantly increased the availability of maintenance treatment and detox treatment; and/or
  - Such Waivers have adverse consequences for the public health.

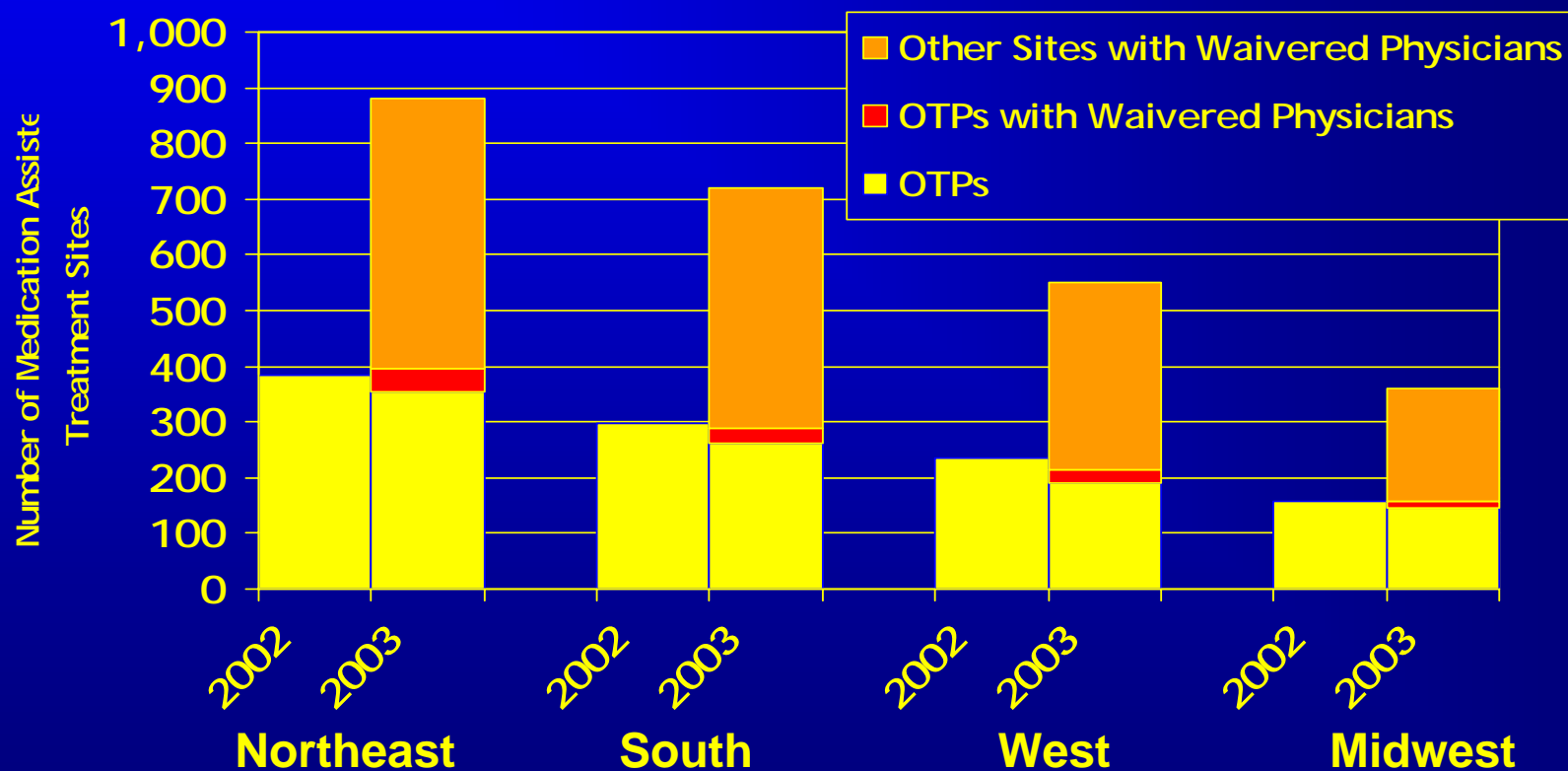
# Key Goals of the SAMHSA Evaluation

Per the supporting legislation—the Drug Addiction Treatment Act of 2000 (“DATA”)—describe the impact of the Waiver program upon:

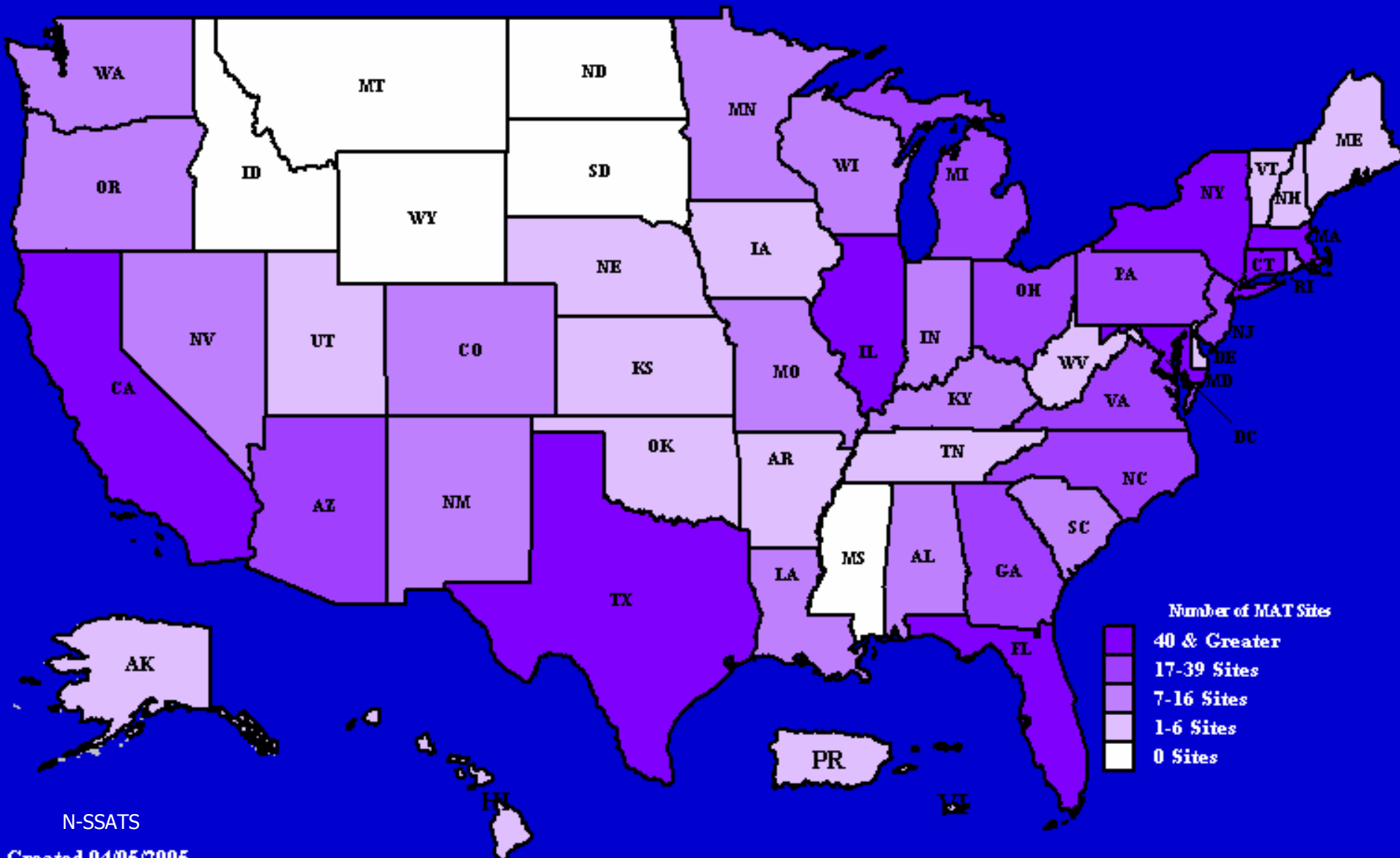
- **AVAILABILITY** of detoxification and maintenance treatments;
- **EFFECTIVENESS** of these treatments; and
- Potential adverse **PUBLIC HEALTH CONSEQUENCES**, including **DIVERSION** activities.

# Medication Assisted Treatment (MAT) Sites by Region, 2002 and 2003

Total MAT sites increased from 1,080 to 2,564



# Concentration of MAT Sites Prior to the Waiver Program (OTPs Only) by State, 2002

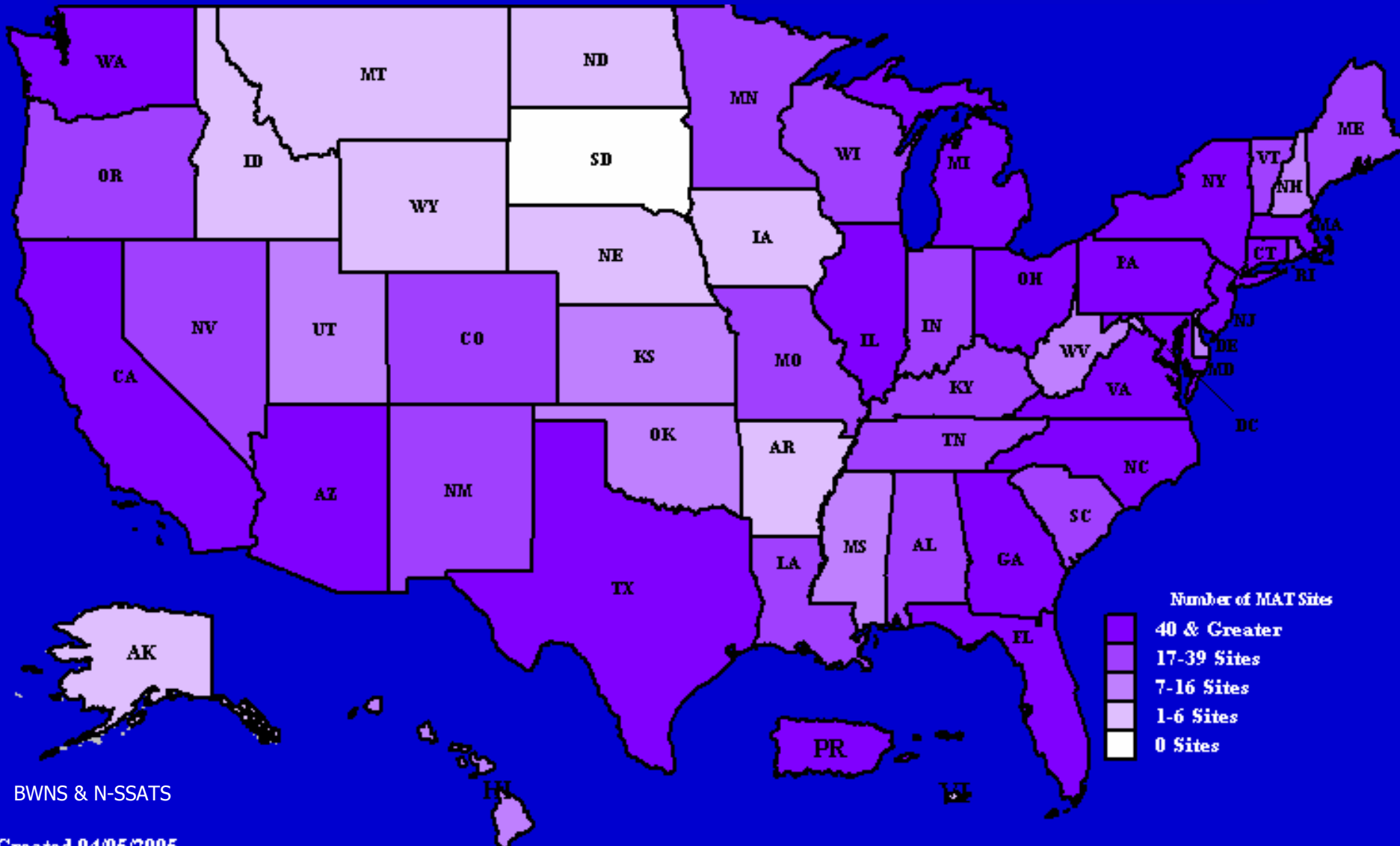


N-SSATS

Created 04/05/2005

SAMHSA/CSAT's Evaluation of the Buprenorphine Waiver Program 2002-2005

# Concentration of MAT Sites After the Waiver Program (OTPs and BUP Waiver Sites) by State, 2003



BWNS & N-SSATS

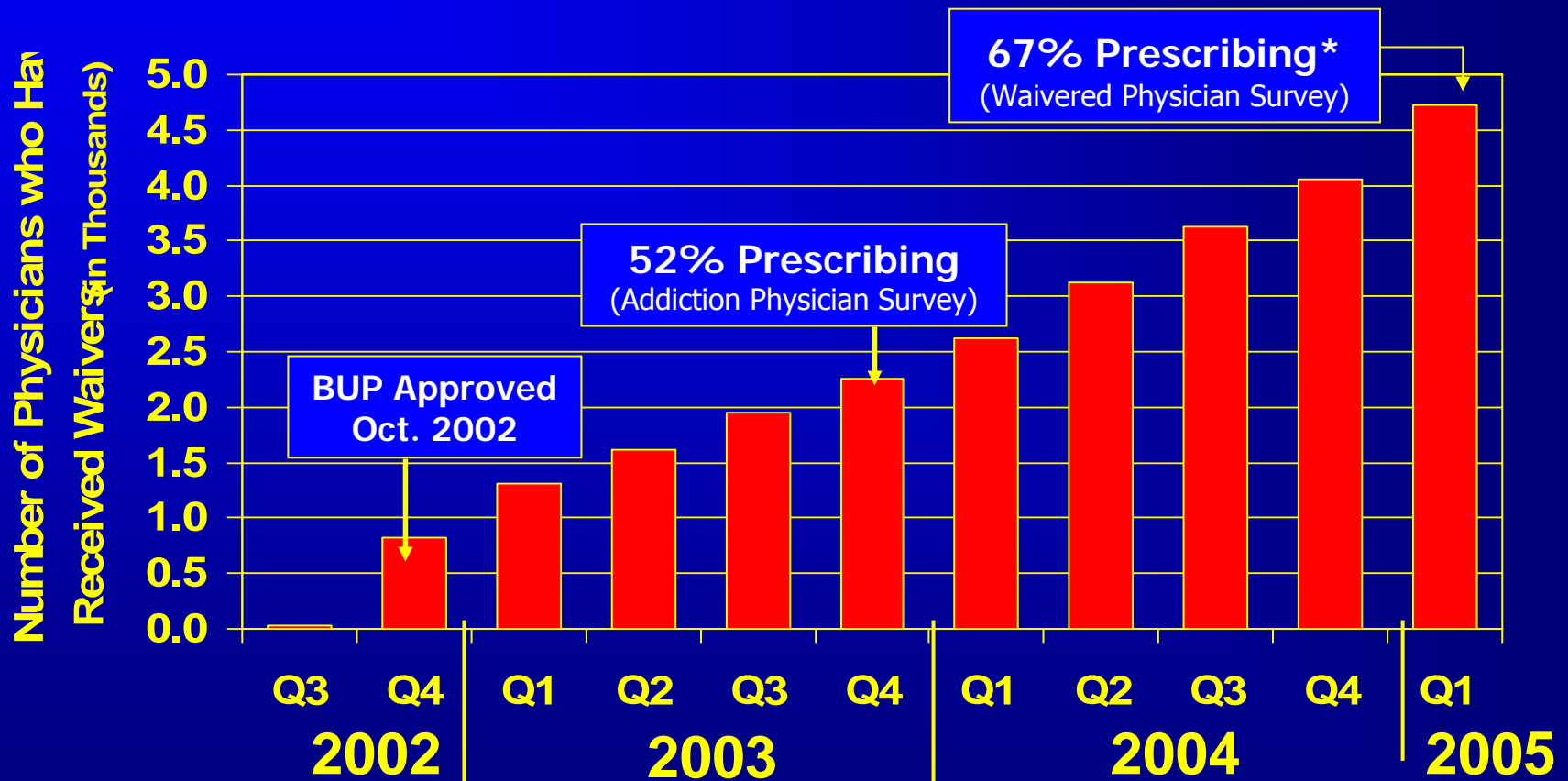
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# The Physicians

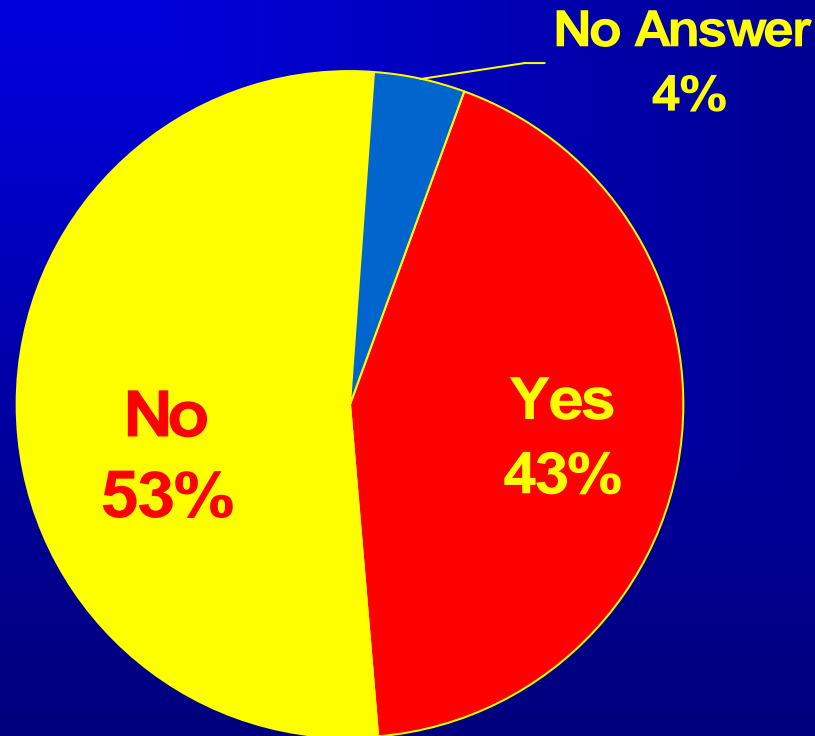
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# Number of Waivered Physicians and Estimated Number Prescribing



# Half of Waivered Physicians Had No Previous Experience Providing MAT, 2005

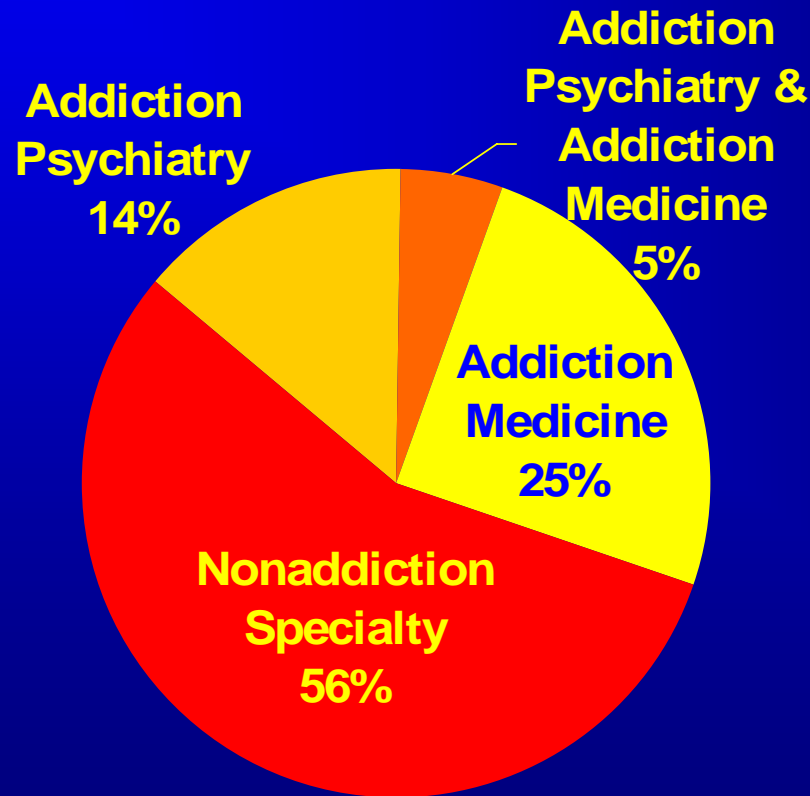
Have you ever provided medication assisted treatment for opioid dependence using methadone?



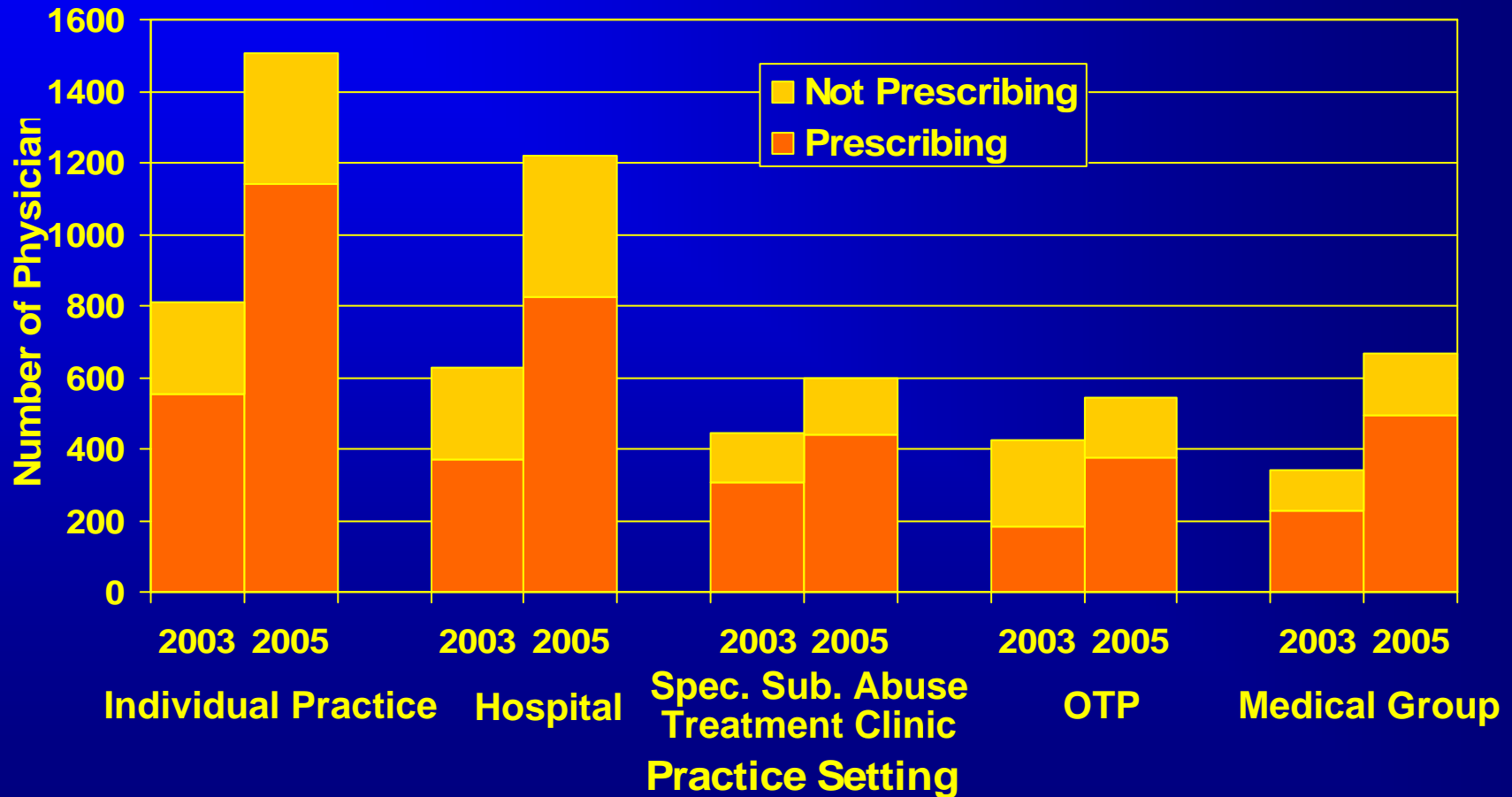
*n*=1,568

# Specialties Reported by Waivered Physicians, 2005

56% *Not* Addictions Specialists



# Practice Setting of Waivered Physicians, 2003-2005



40% and 43% of the sample worked in more than one practice setting in 2003 and 2005 respectively

# Summary on Treatment Availability and Waivered Physician Characteristics

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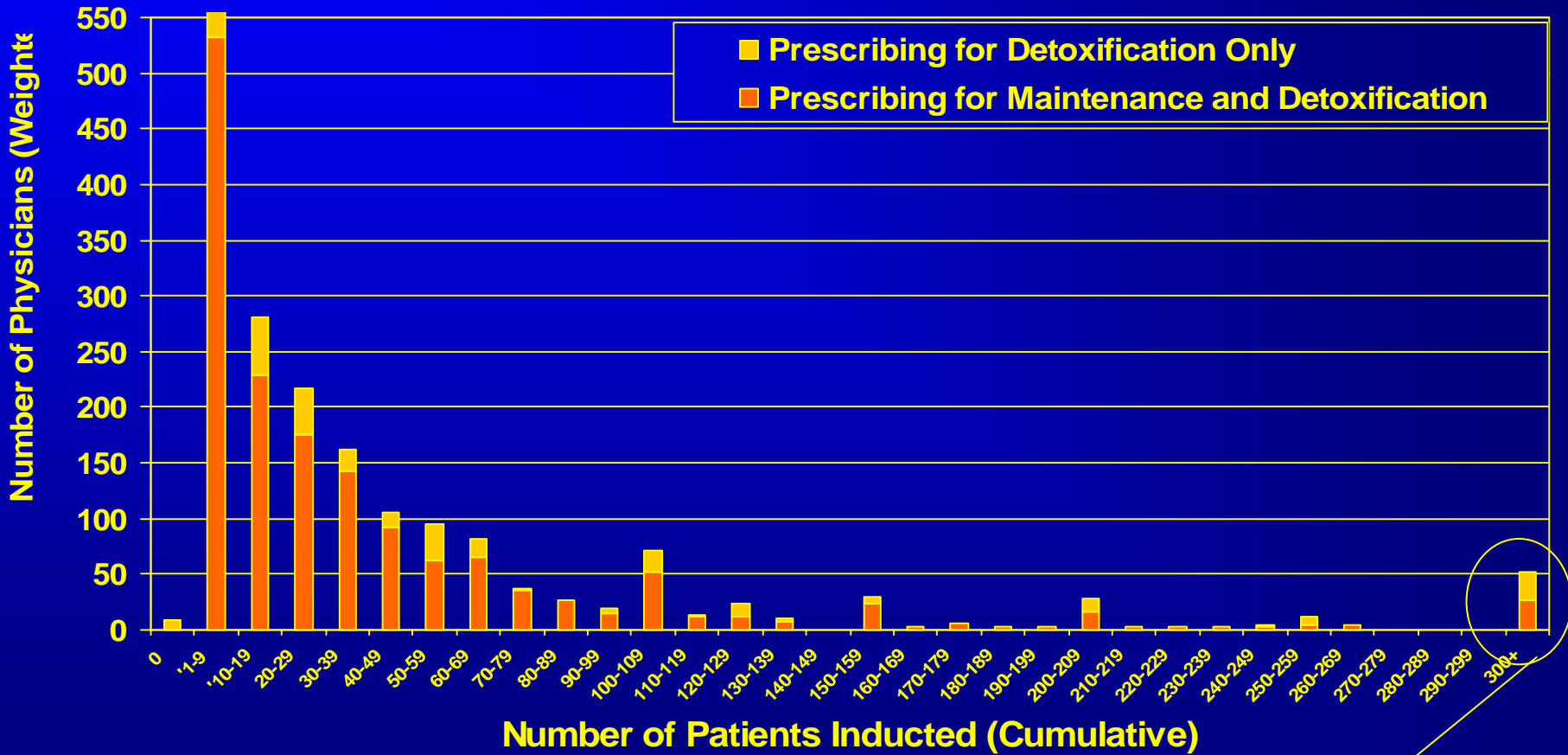
- Geographic availability increased from 2002 to 2003, following the introduction of the DATA Waiver Program.
- From 2003 to 2005, the number of waivered physicians increased significantly, as did the proportion prescribing.
- Many waivered physicians were not addiction specialists.
- Waivered physicians were working in a range of settings — especially hospital and specialty substance abuse treatment centers — beyond the individual office-based settings originally envisioned.
- Hospitals and specialty substance abuse treatment centers were together treating more patients than physicians in individual practice.

**Highlights:**

**What Treatment Looked Like**

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# Patients Inducted per Prescribing Physician, 2005



More than 50 physicians reported inducing more than 300 patients



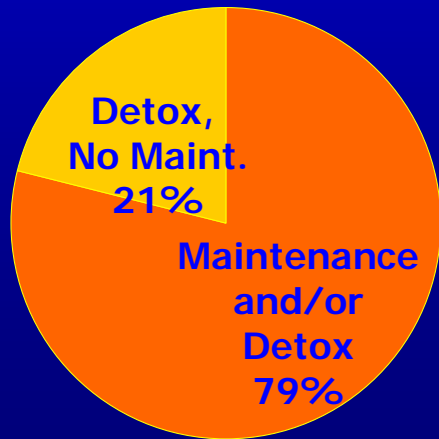
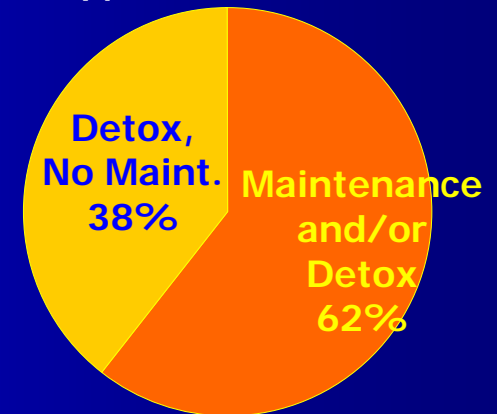
# Twenty-three Percent of Prescribers Use BUP for Detoxification but not for Maintenance in 2003 and 2005

Physicians Providing Each Type of Treatment



2003

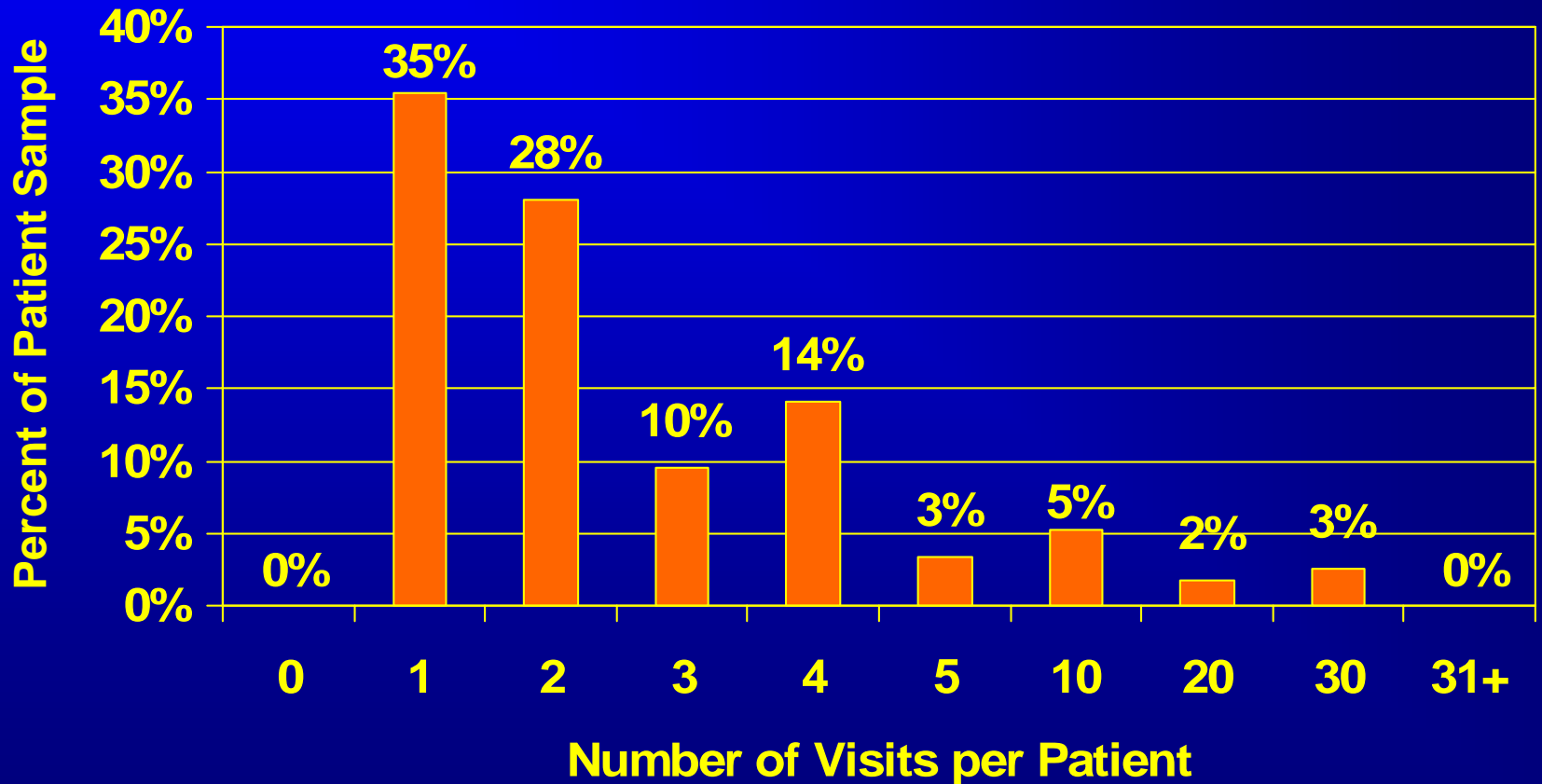
Patients Treated in Each Type of Practice



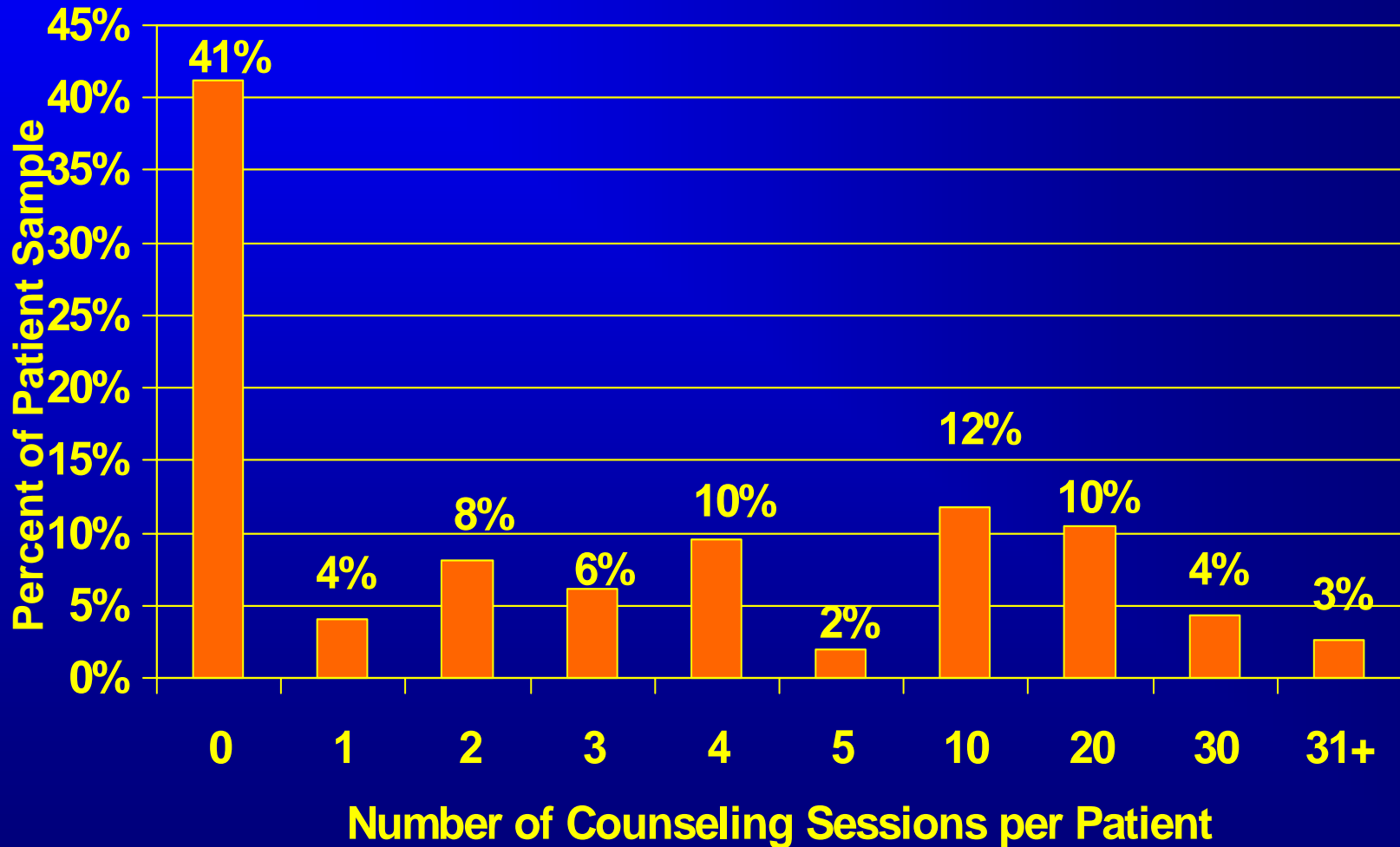
2005



# Patient Reports of Visits to Physician Providing BUP in First 30 Days of Treatment



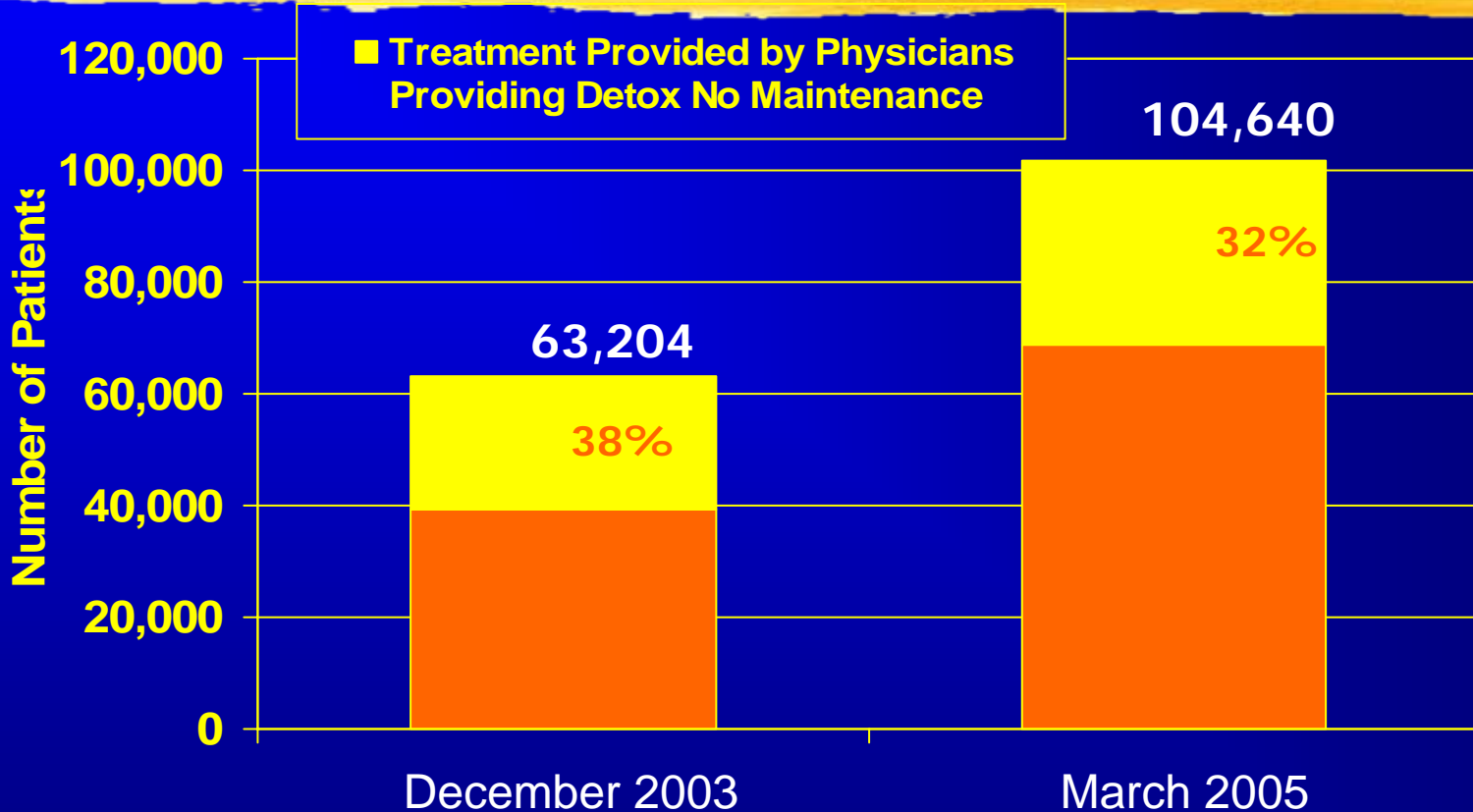
# Patient Reports of Substance Abuse and Mental Health Counseling Sessions in First 30 Days



# The Patients

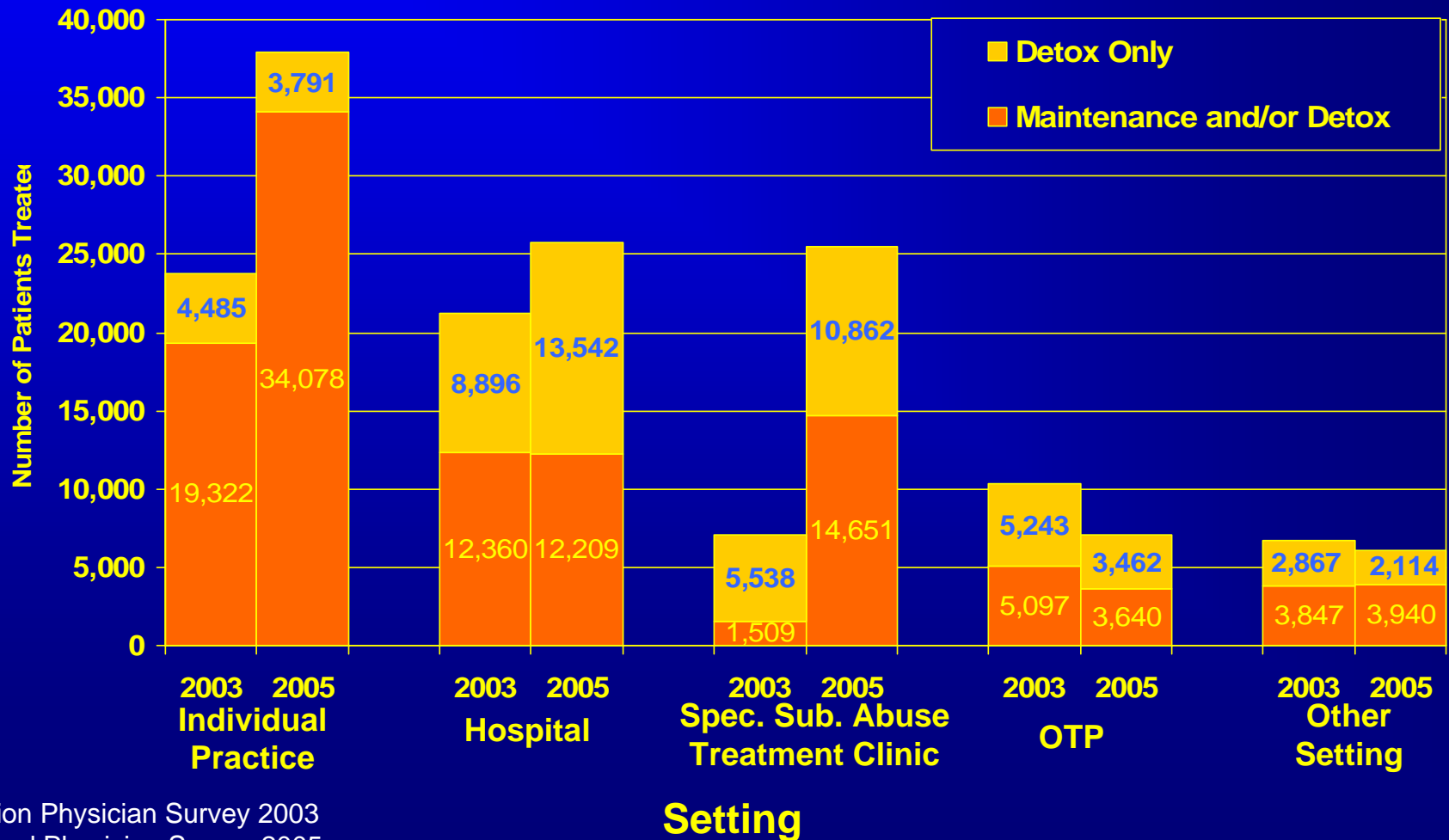


# Cumulative Estimate of Number of Patients Inducted

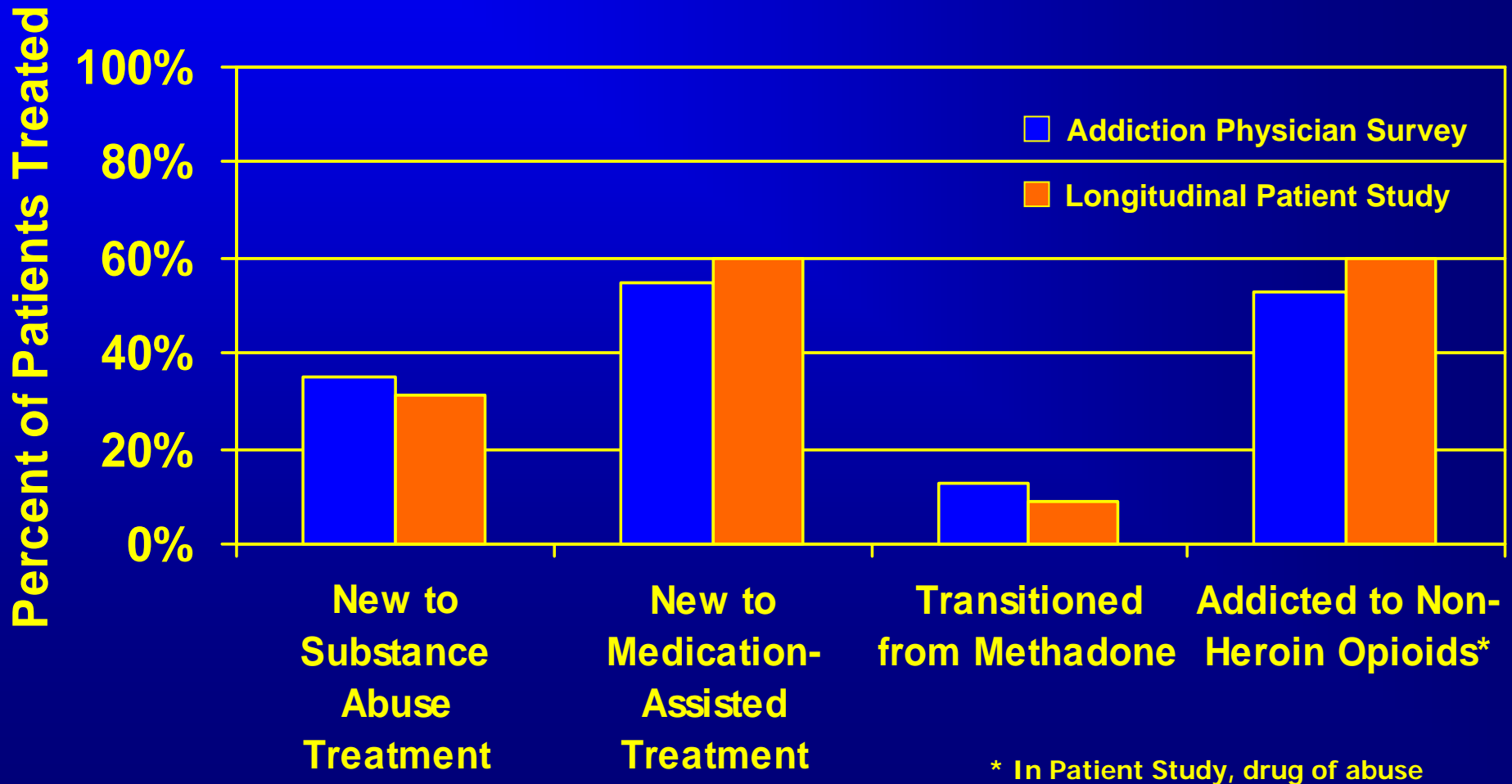


Mean # of Patients/Physician	57	46
SD	6	147
Range	1-800	1-1011

# Patients Inducted by Setting and Treatment Offered

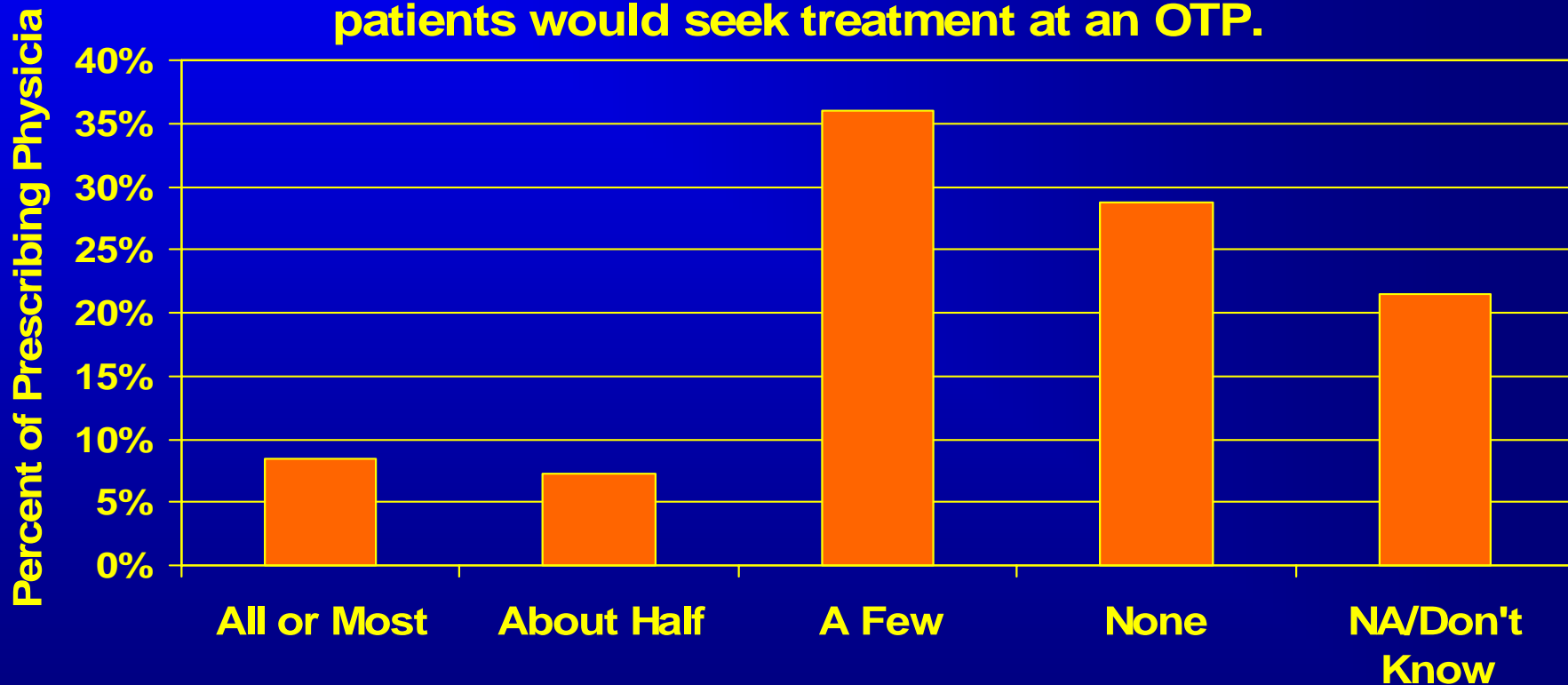


# Characteristics of Patients Treated Under the Waiver Program



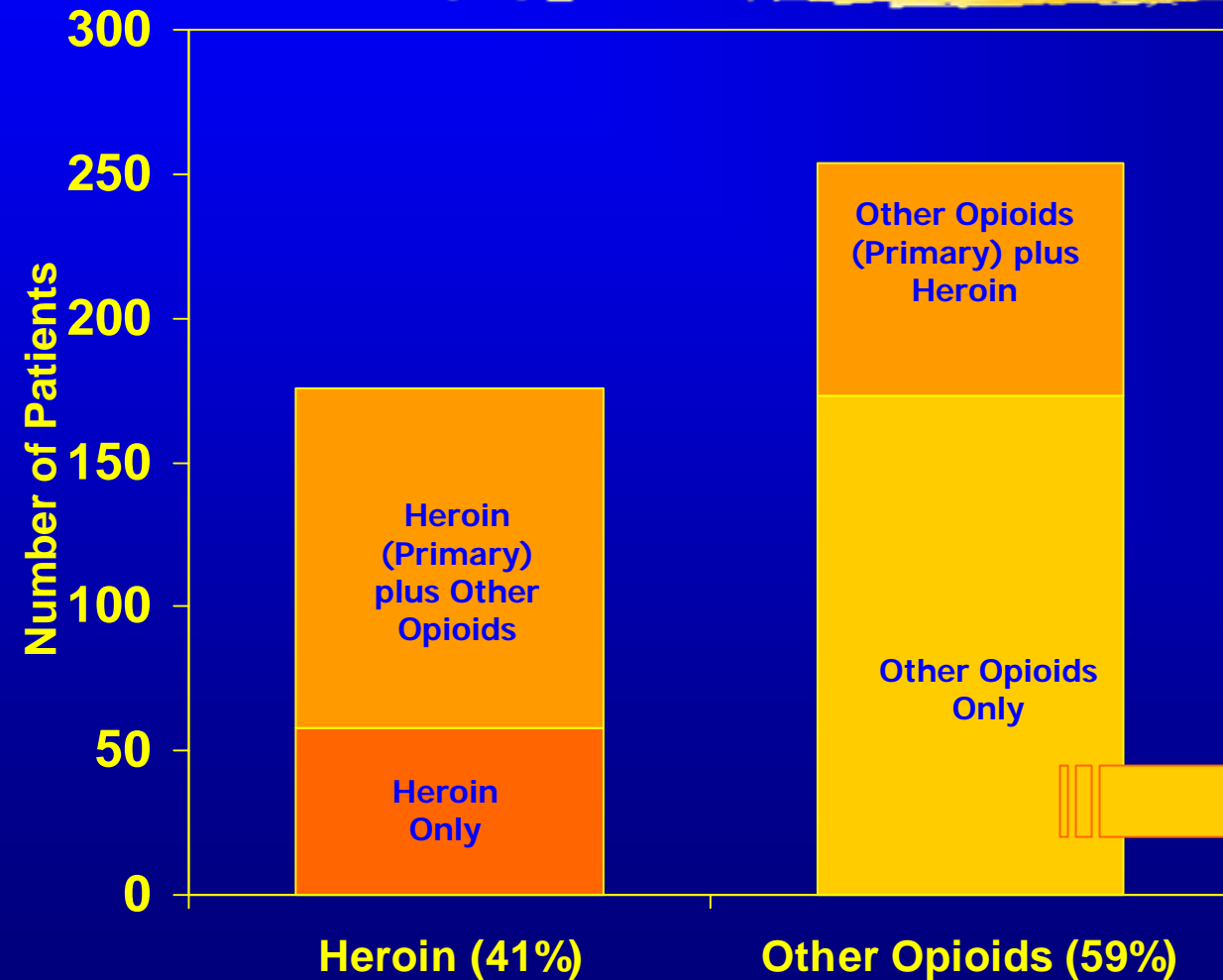
# Physicians Report Few BUP Patients Are Willing to Attend OTPs

Only 10% of physicians believed that at all or most of their patients would seek treatment at an OTP.





# Primary Opioid Abused And the Regular Problematic Use of Other Opioids



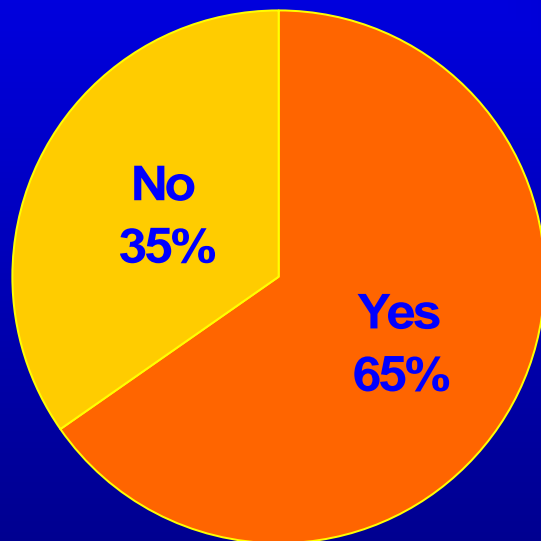
40% of the sample limit their abuse to non-heroin opioids.

Individuals with abuse limited to non-heroin opioids may represent a distinct patient subpopulation seeking treatment in BUP sites.

Primary Opioid Abused 30 Days Prior

# Patients Abusing Substances Other Than Opioids

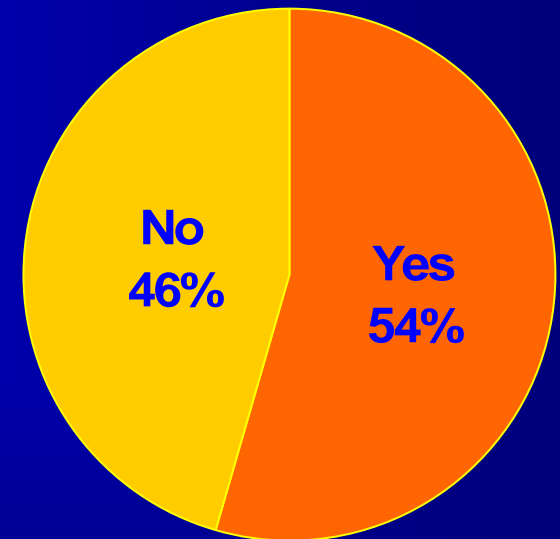
## Patient Study 2004-05



Proportion of Patient Study sample reporting at least one day of use in the past 30 of nonopioid drugs or binge alcohol

*N*= 433 patients

## Waivered Physician Survey 2005

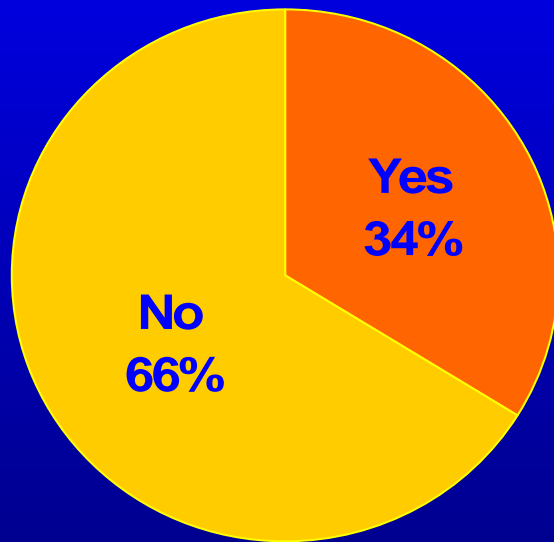


Estimates based on physicians' report of proportion of inducted BUP patients having comorbid substance abuse disorders

*n*= 1,034 physicians

# Chronic Pain Patients Are an Important Subpopulation Treated With BUP

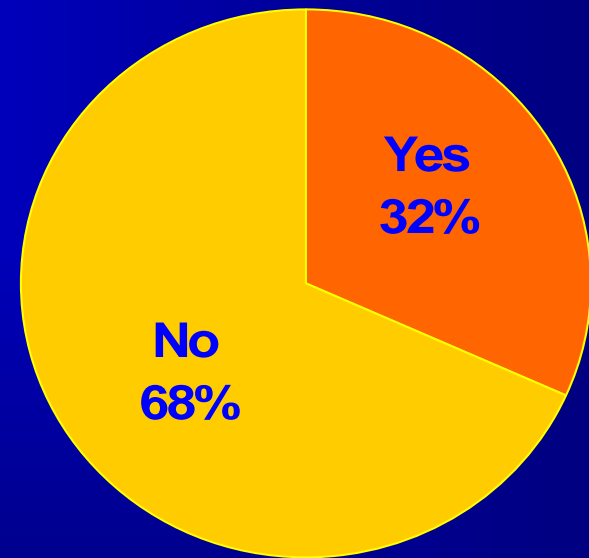
## Waivered Physician Survey 2005



Estimates based on physicians' report of proportion of inducted BUP patients who "suffered from a chronic pain syndrome."

*n*= 1,034 physicians

## Patient Study 2004-05



Proportion of Patient Study sample reporting that they had been "diagnosed with chronic pain" (lifetime).

*n*= 411 patients

# Patient Satisfaction, 6-Month Outcomes

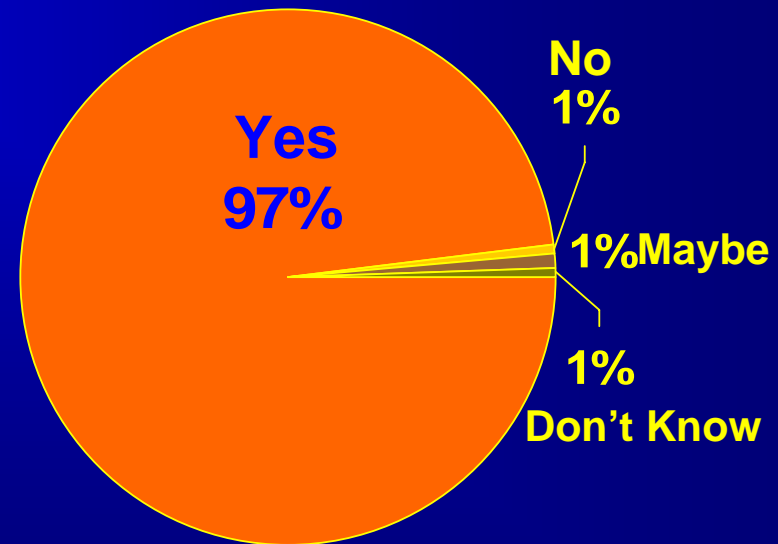


# Patients Are **Satisfied** With BUP Treatment at 6 Months

"Overall, how would you rate the helpfulness of BUP as a medication for opioid addiction?"

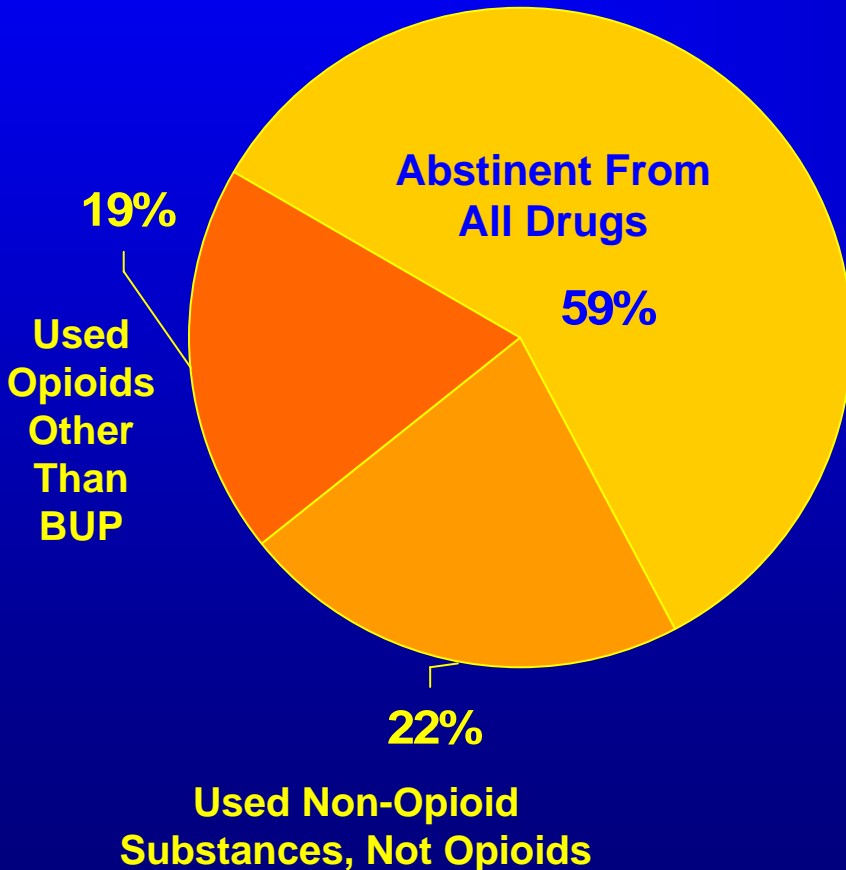


"Would you recommend BUP treatment to a friend suffering from opioid addiction?"



# 6 Month BUP Treatment Outcomes: **Abstinence** From Drugs During Past 30 Days

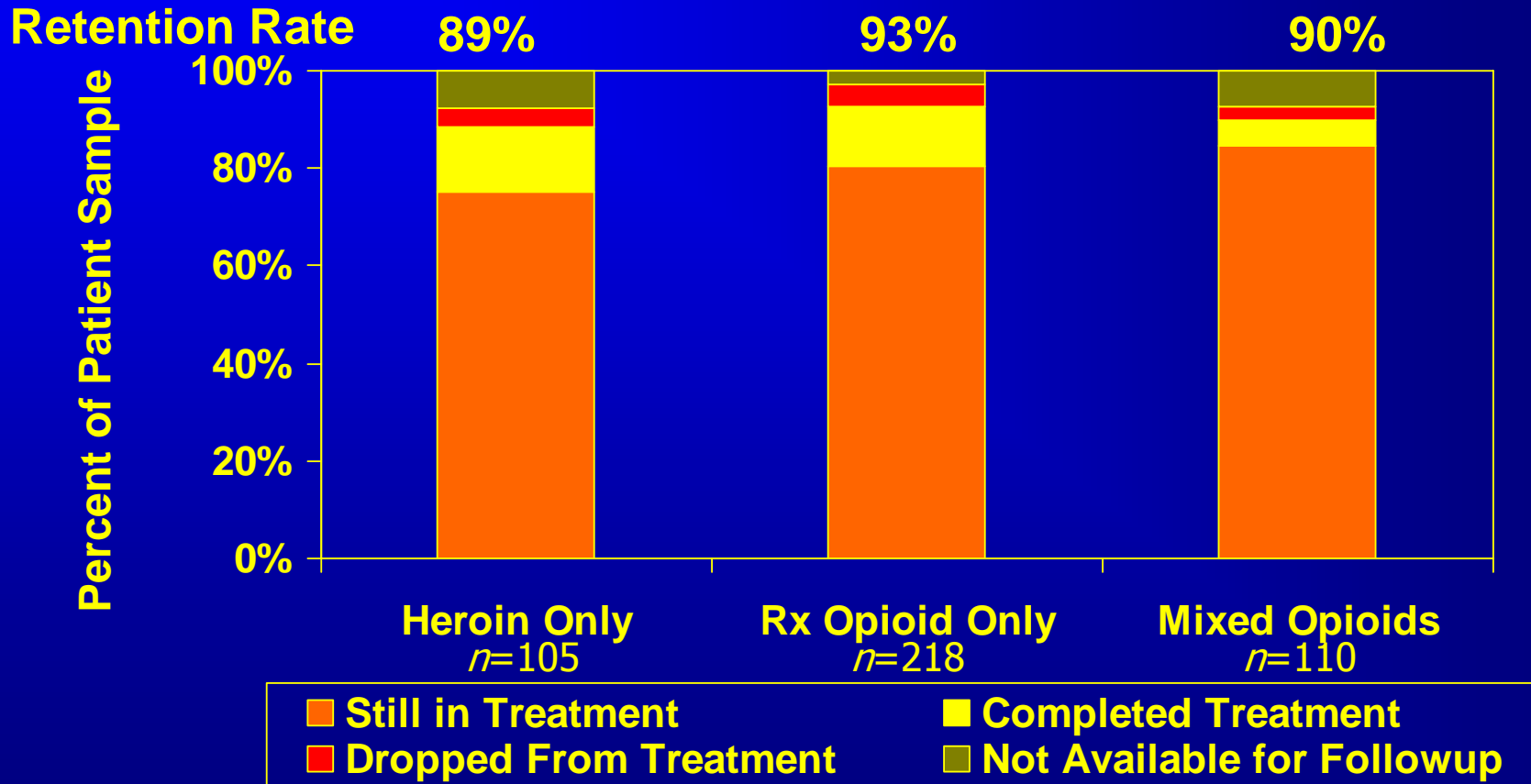
(Self-Reported)



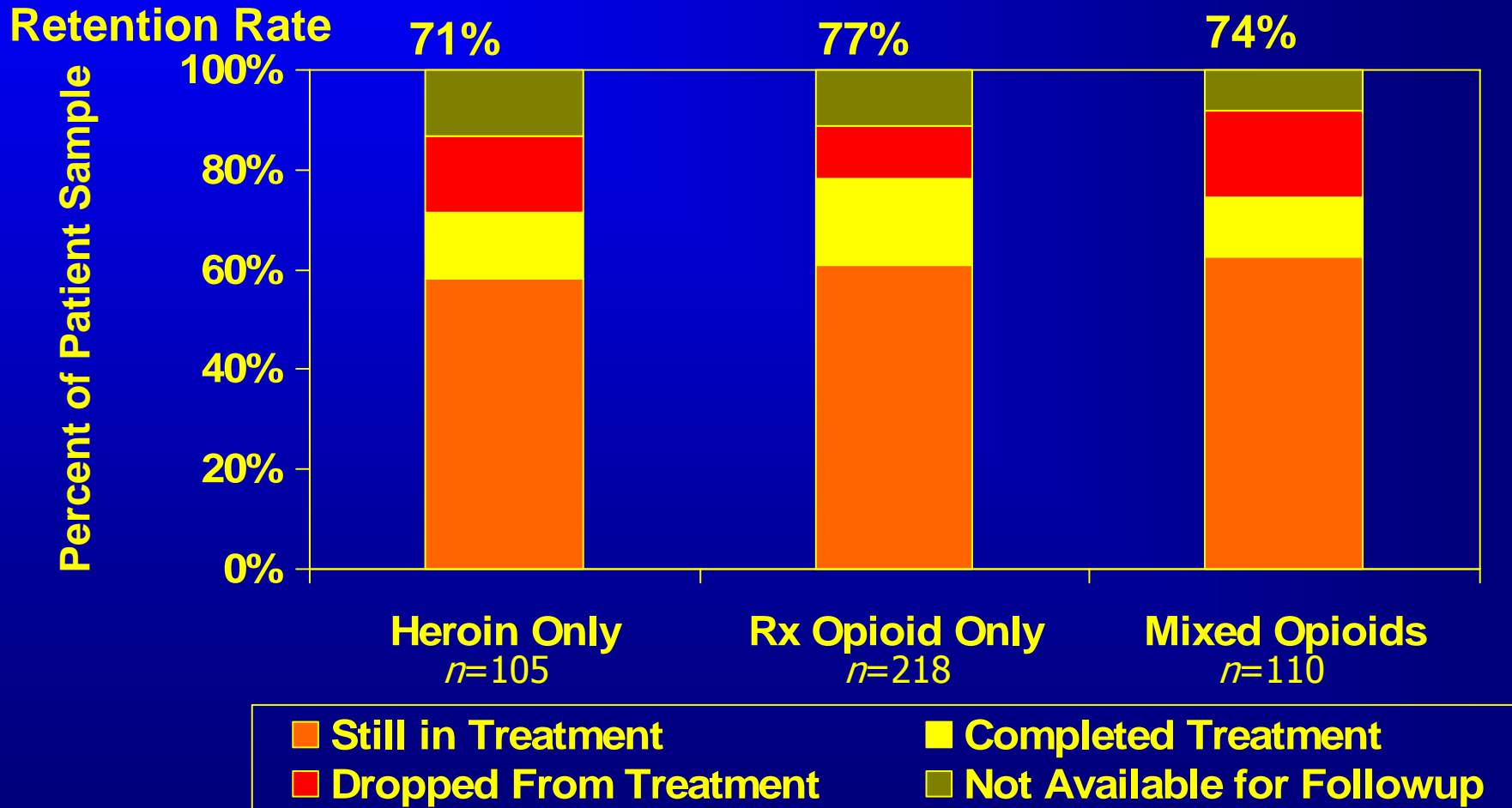
59% Abstinent From All Drugs

81% Abstinent From Opioids (except BUP)

# BUP Treatment Retention at 30 Days

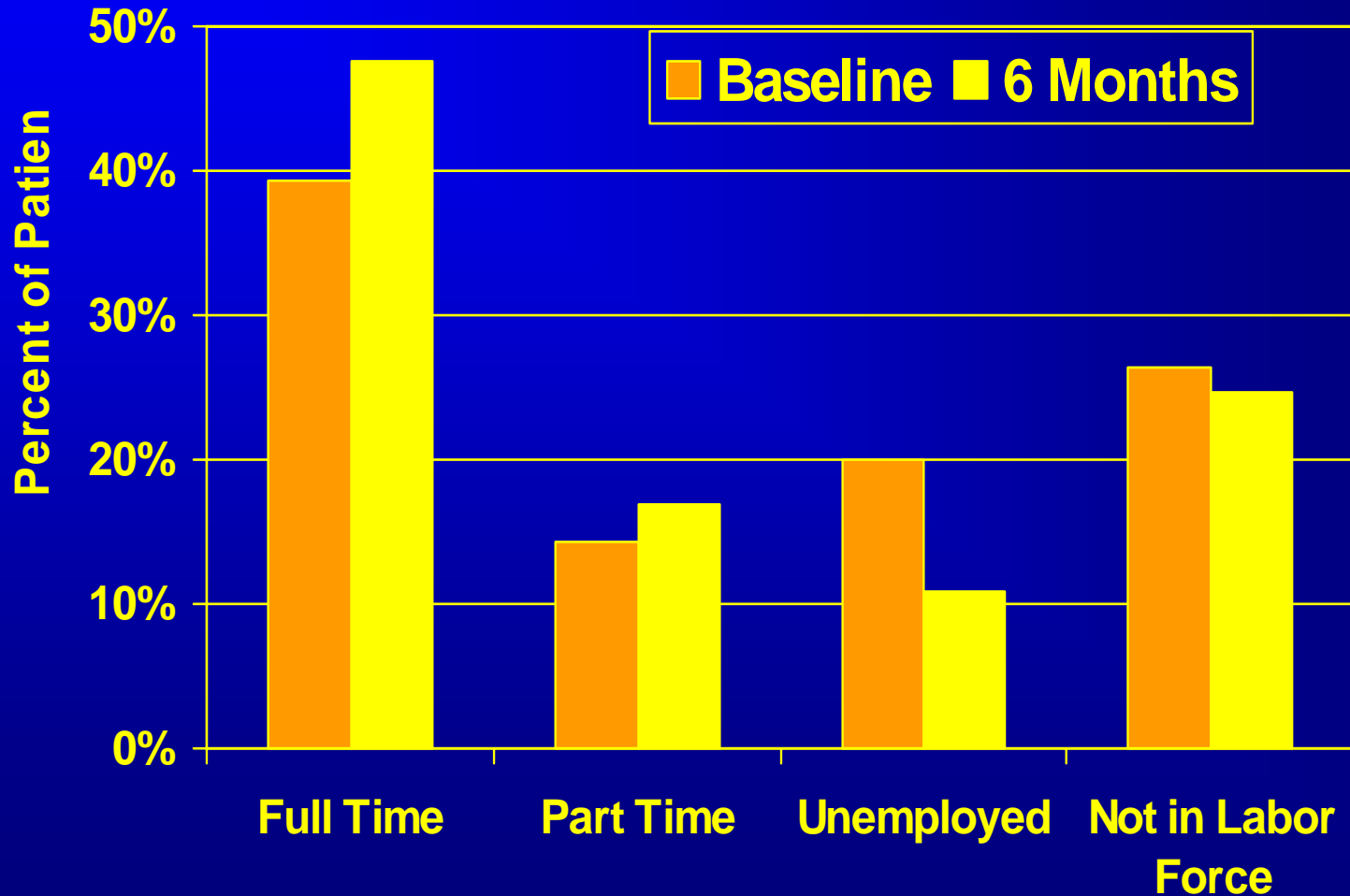


# BUP Treatment Retention at 6 Months



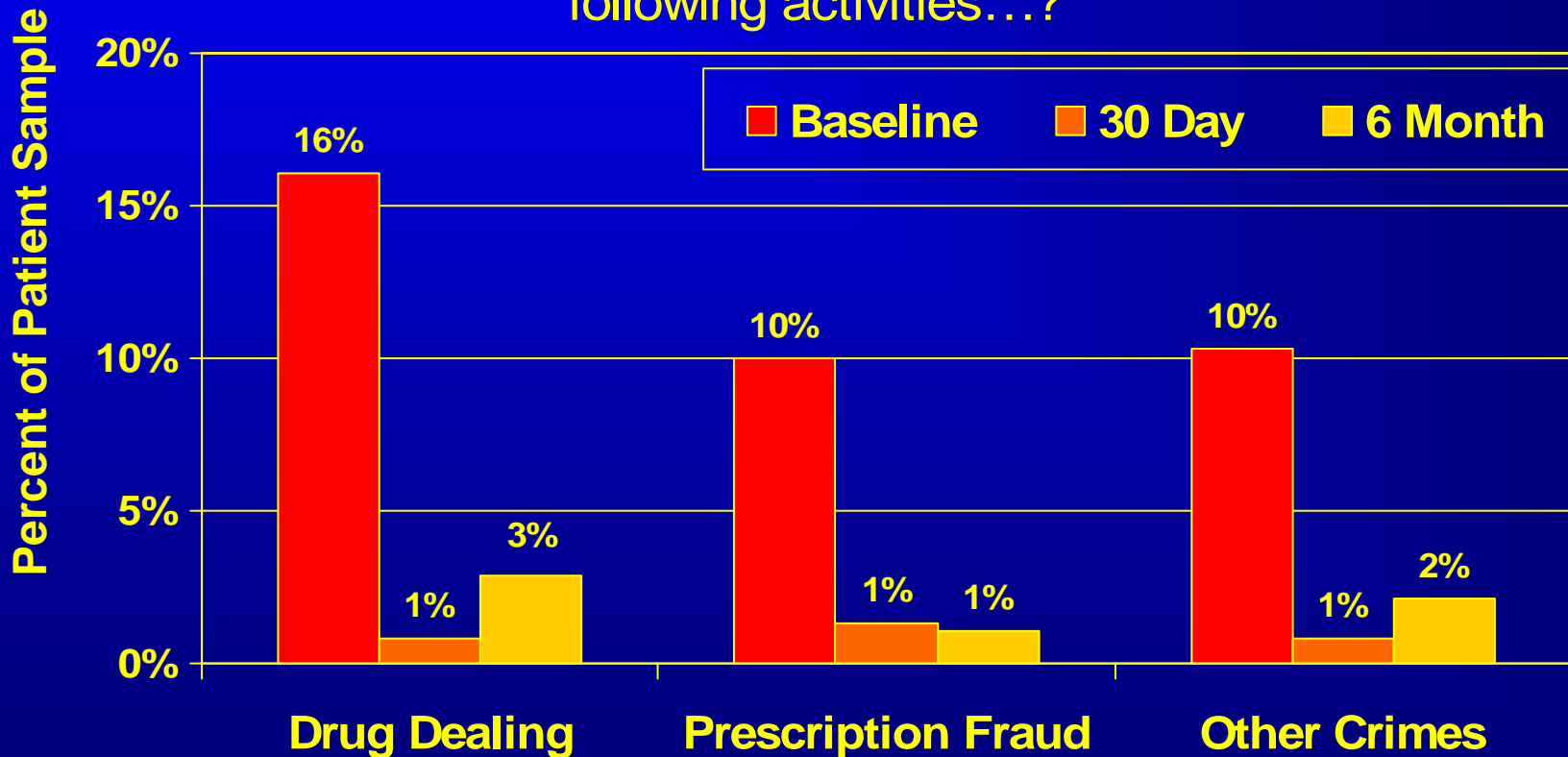


# Patient Outcomes: Employment at Baseline and 6 Months

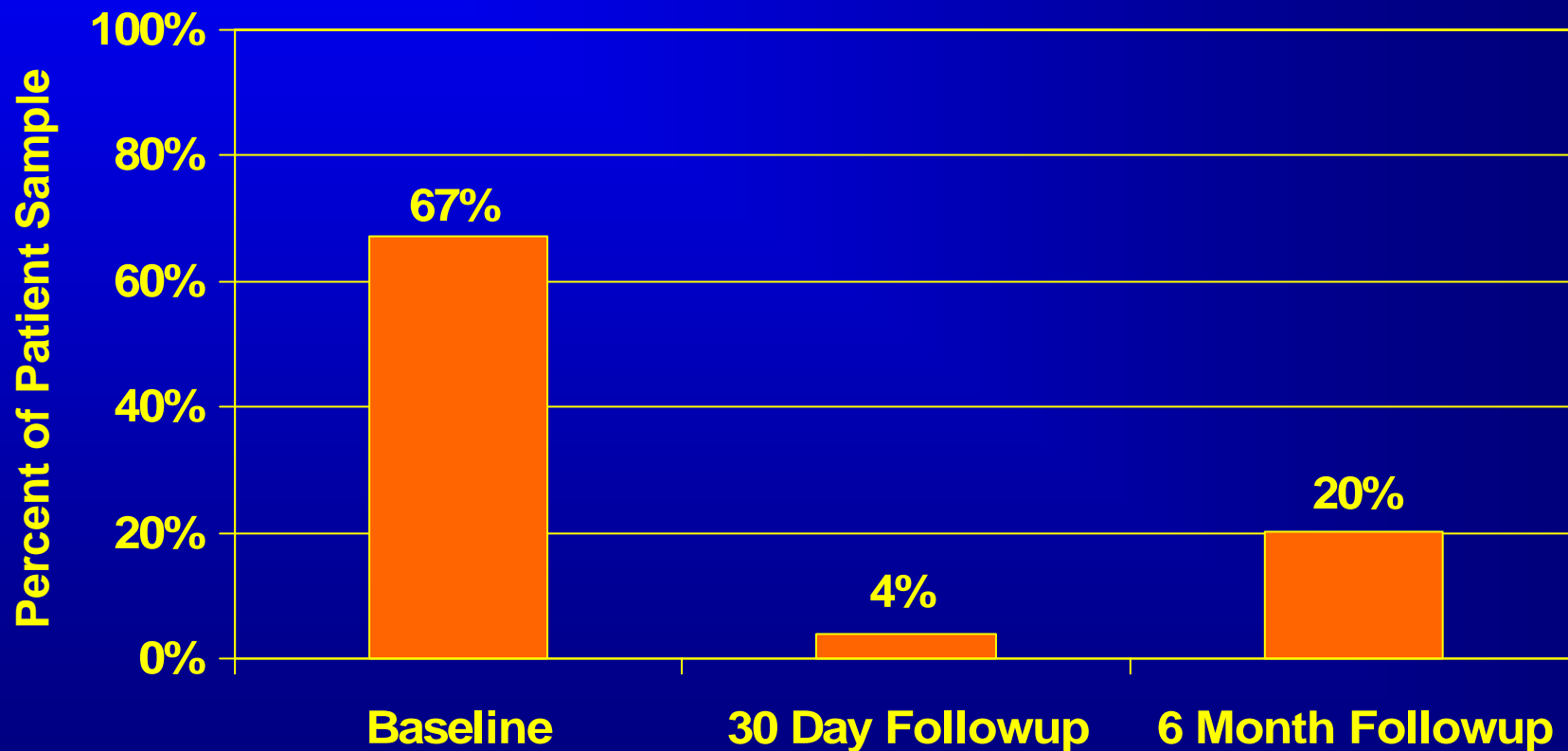


# Patient Outcomes: Specific Criminal Activities

“In the past 30 days were you involved in any of the following activities...?”

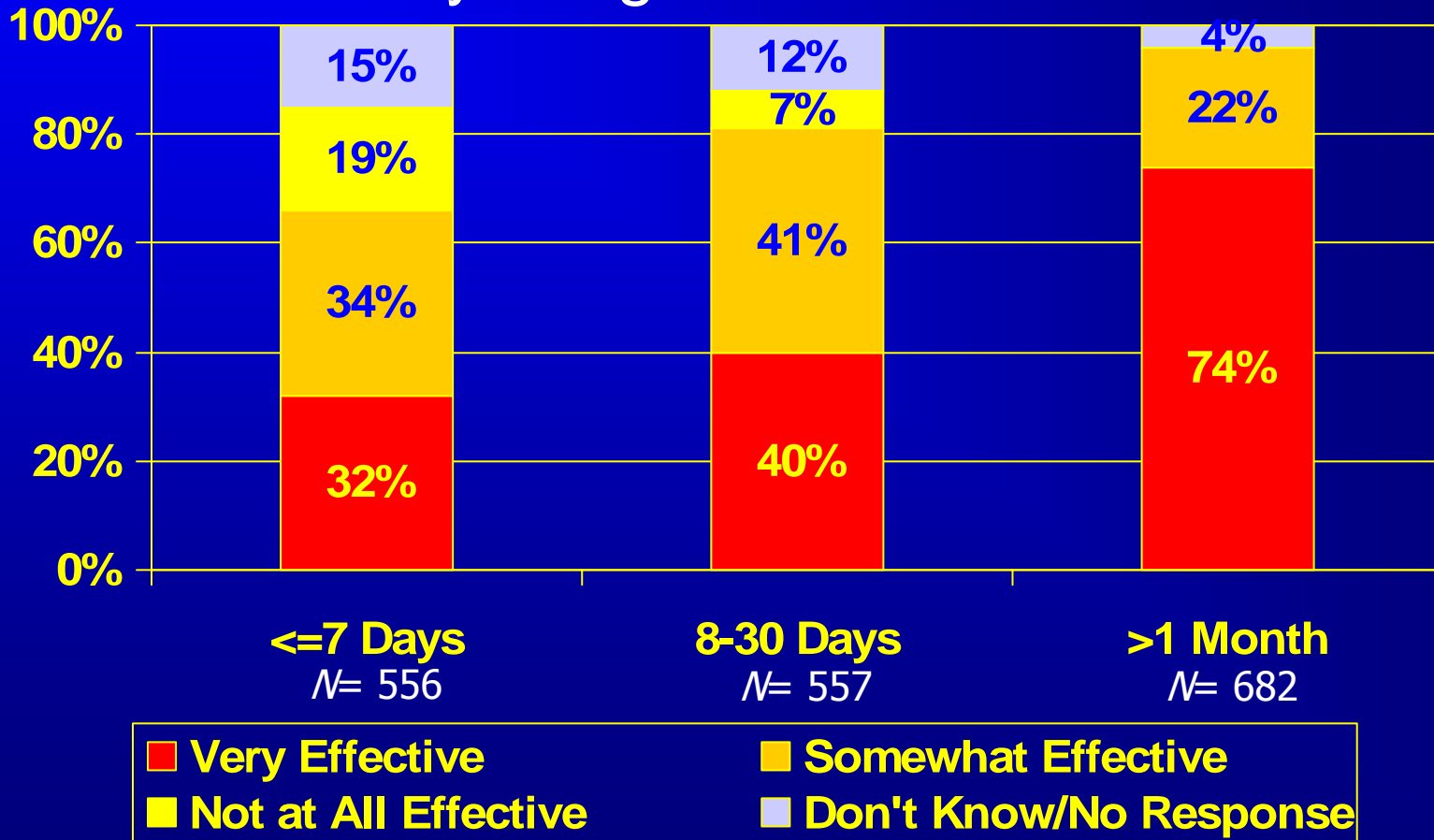


# Patient Outcomes: Percent of Patients Acquiring Drugs on the Street



# Prescribing Physicians'\* Perceptions of BUP Effectiveness, 2005

## By Length of Treatment



\*Views of physicians who reported some experience treating for that length of time

# Summary on Outcomes & Effectiveness

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- Most prescribing physicians perceived BUP to be effective, particularly for longer treatment lengths.
- Positive treatment outcomes were observed among patients treated in a range of **real-world** practice settings.
- Outcomes are consistent with and comparable to the results of numerous clinical trials that have found BUP to be effective in research contexts. In addition:
  - BUP appeared to be somewhat more effective for patients dependent on prescription opioids than for those primarily dependent on heroin.
  - BUP appeared to be as effective for persons with chronic pain as for those who had not been diagnosed with chronic pain.

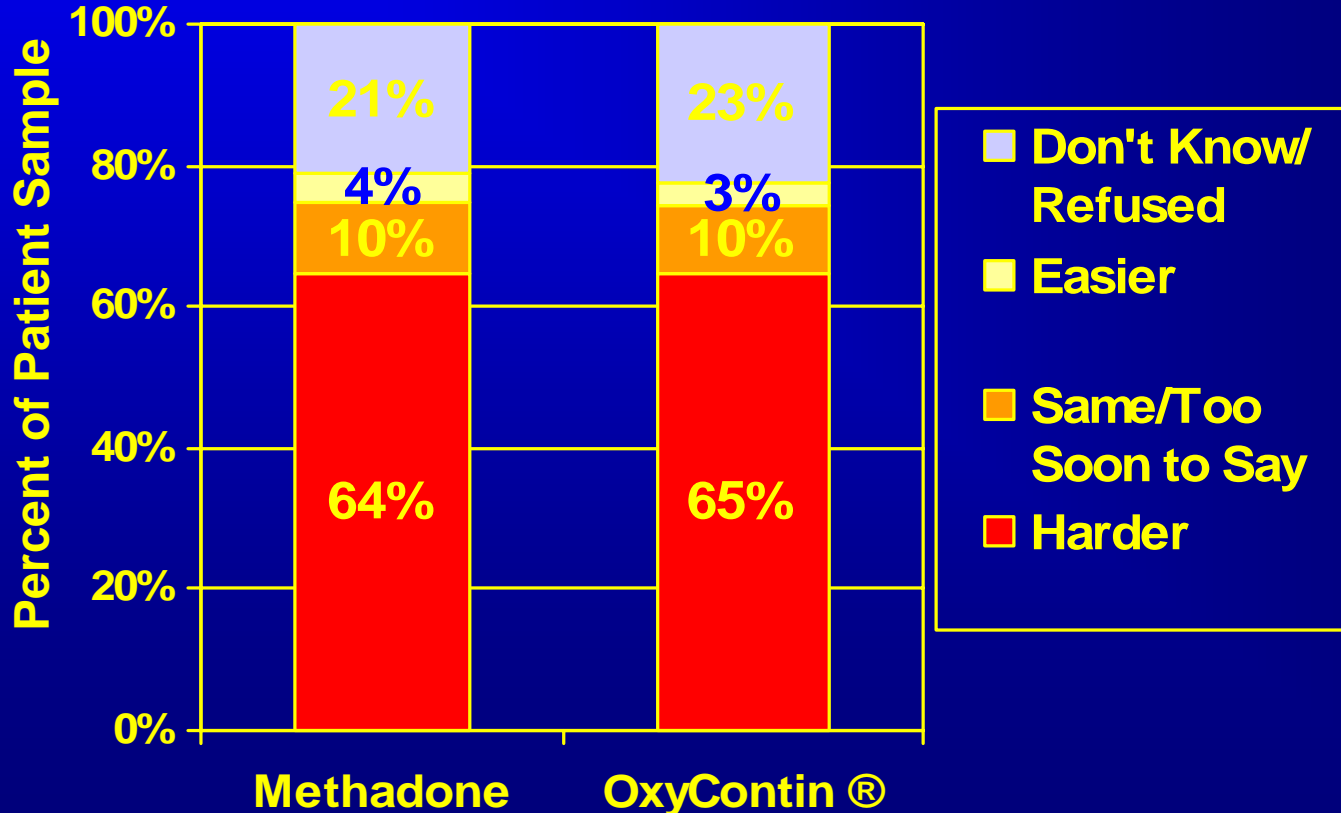
# **“Adverse Events,” Public & Individual**



# Patient Reports of **Diversion**, 2005

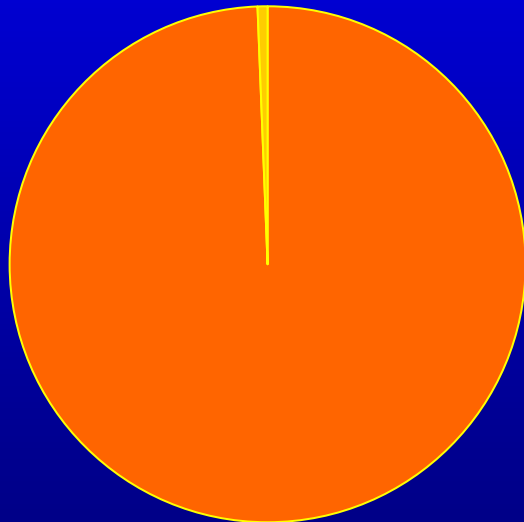
“Compared to **OxyContin®** or **methadone**, how easy or hard do you think it is to buy or sell BUP on the street?”

Responses were similar at baseline and 6 month followup.



# Physicians' Report of Severe Adverse Reactions to BUP Treatment are Rare: 2005

Physicians Report  
0.5% of Patients  
Experienced Severe  
Adverse Reactions

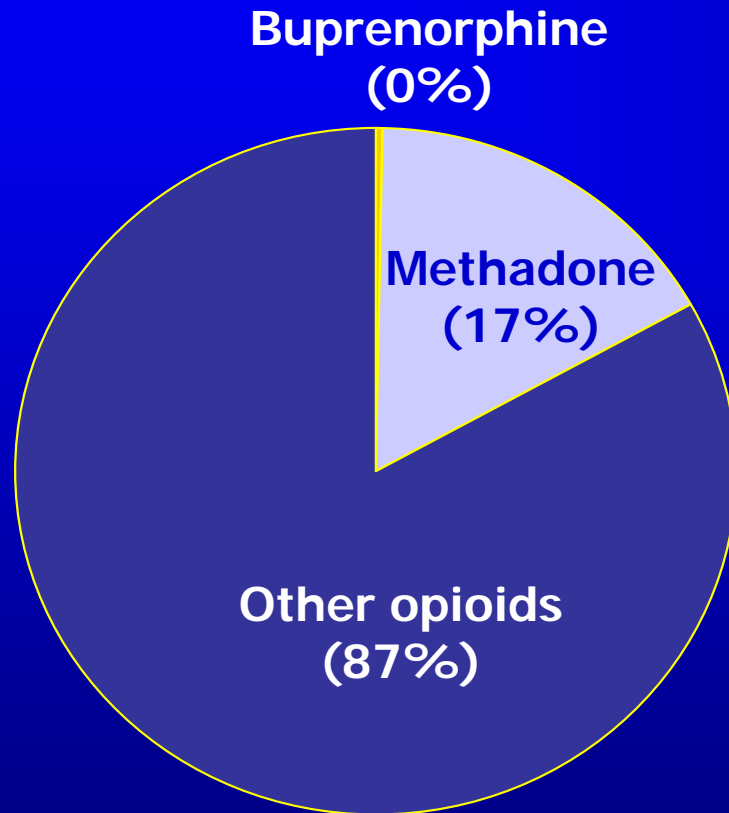


- Specific Reactions Reported (unweighted):
  - Withdrawal: 103
  - Allergic reactions: 12
  - Respiratory depression: 9
  - Drug interactions: 9
  - Liver problems: 2
  - Renal insufficiency (or aggravation of it): 2
  - Unspecified: 80

*Physicians reported 217 patients with severe adverse reactions, out of a total 47,664 patients inducted (unweighted).*



# BUP Is Rarely Mentioned in DAWN Emergency Department Visits, 2004

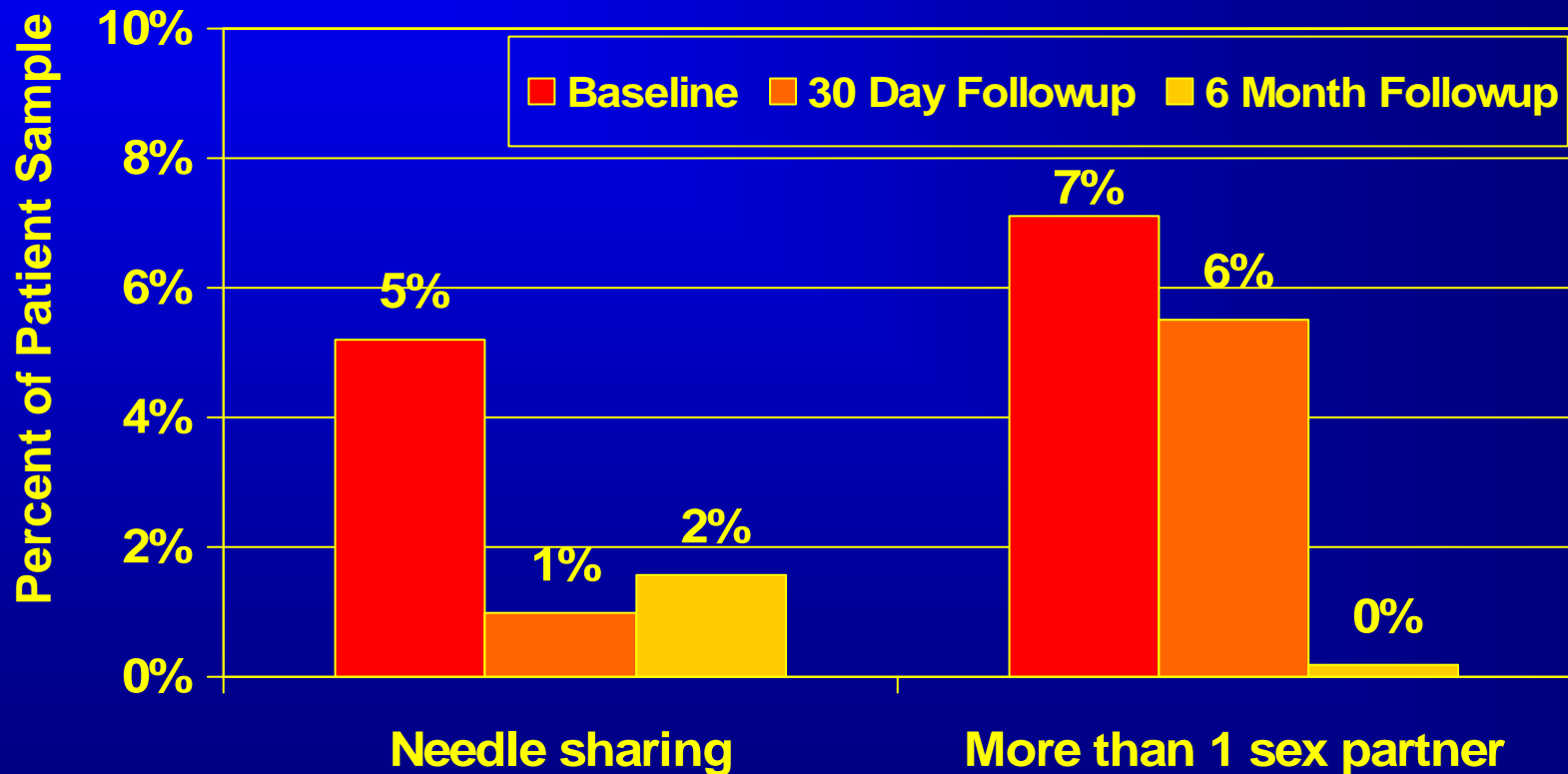


Only 108 ED visits  
involved BUP (0.04%)

- 30 adverse reactions
- 21 seeking detox
- 9 overmedications
- 1 accidental ingestion

Overall, opioids were reported in only 13% of drug-related emergency department visits, often in combination with other substances

# Patient Outcomes: Risky Behaviors



# Summary on Public Health Consequences

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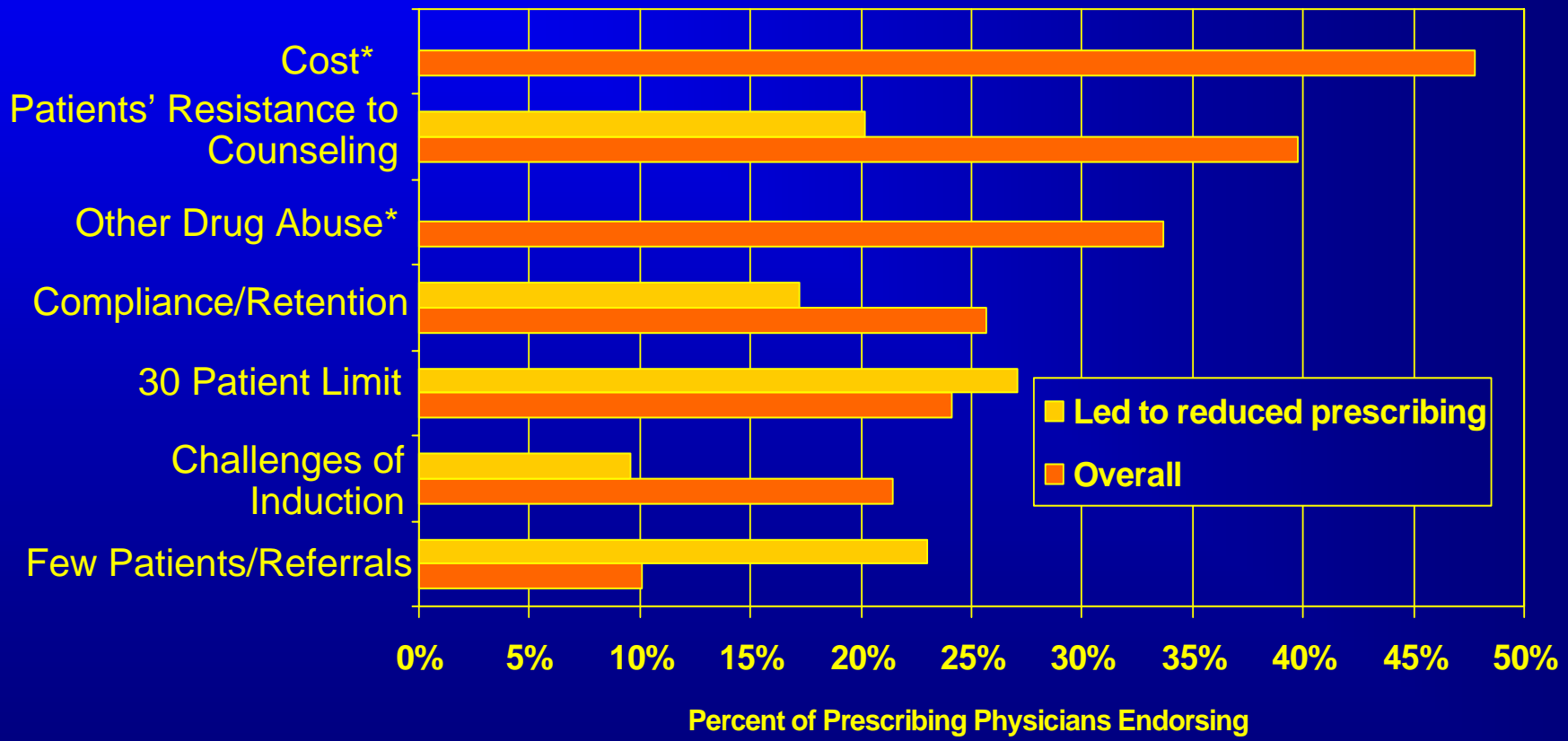
- Early after the start of the DATA Waiver Program, the Evaluation found no indication of significant diversion of BUP.
- Severe adverse reactions were rare.
- There were significant reductions in risky health behaviors.

# Issues and challenges



# Top Challenges to Prescribing BUP and Reasons for Reducing Number of Patients Treated, 2005

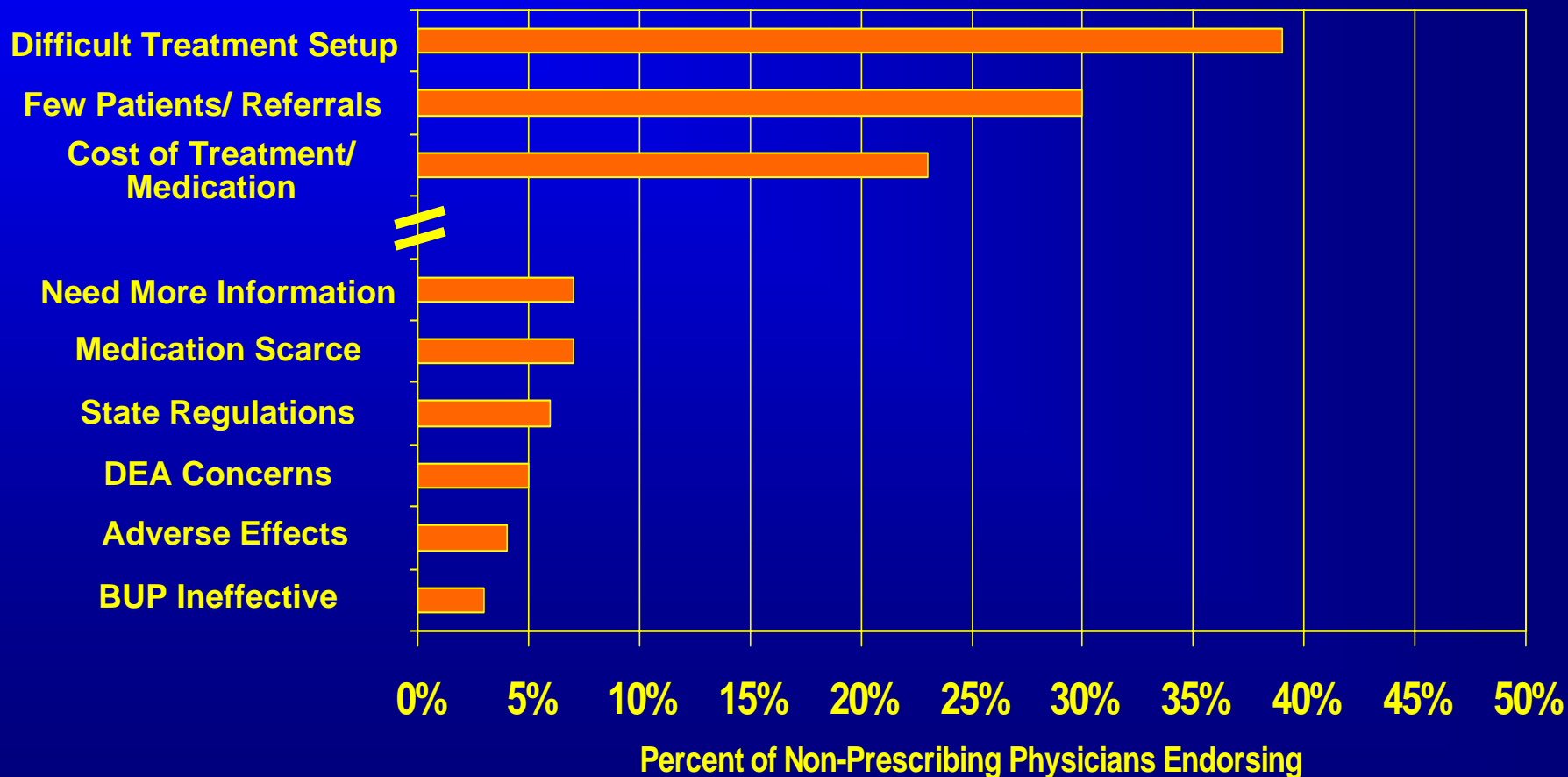
## Challenges most frequently mentioned by prescribing physicians



\* Item only asked for one category

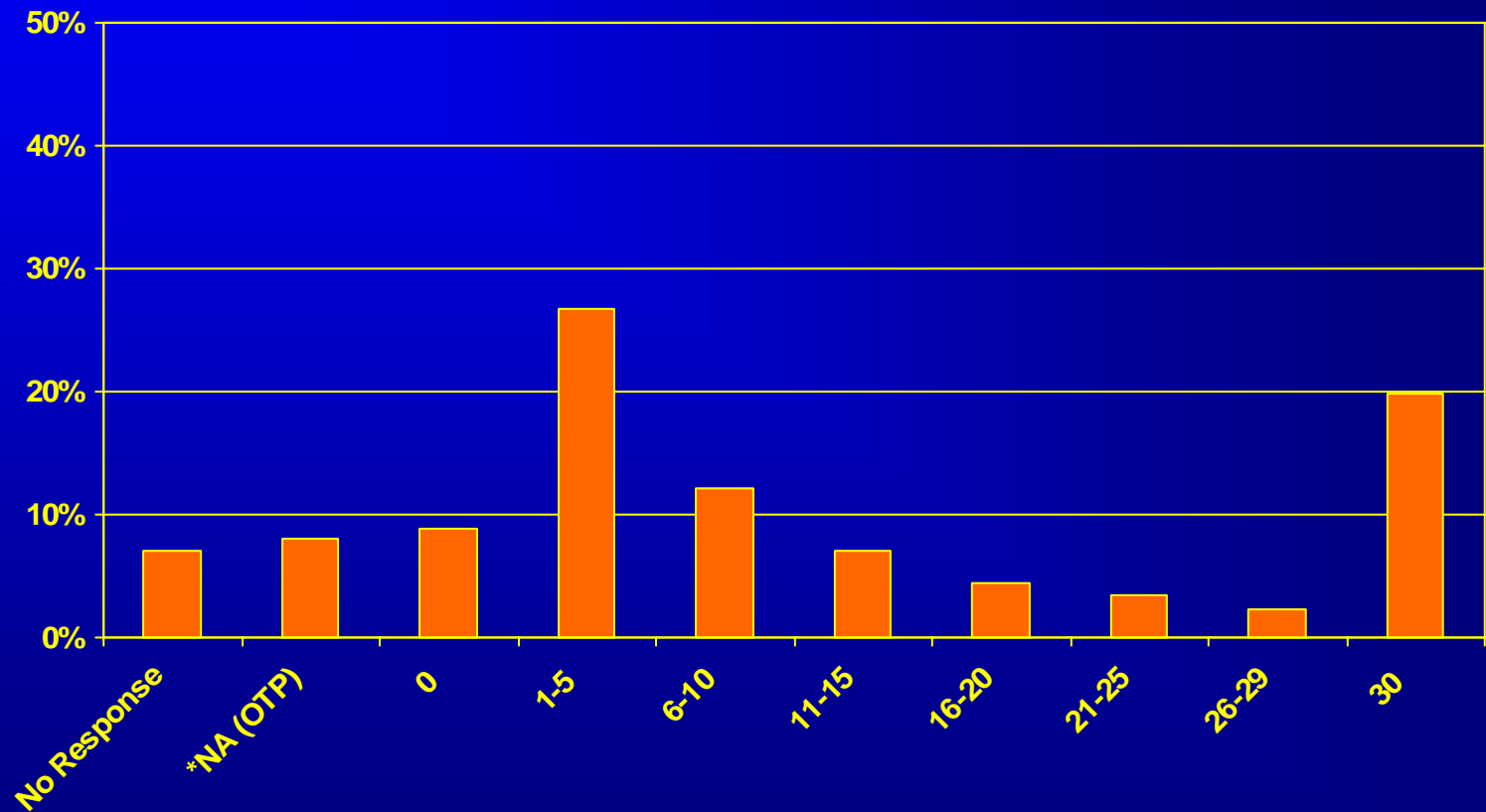
# Barriers to Prescribing Reported by BUP Non-prescribers, 2005

Challenges most or least frequently mentioned by NON-prescribing physicians



# Most Prescribing Physicians Treat Well Below 30 Patient Limit, 2005

Percent of Prescribing Physicians



Number of BUP Patients in Treatment per Practice, 2005

\*Opioid treatment programs are not subject to the 30 patient limit.

# Physician Comments on the 30 Patient Limit, 2005

## Comments Provided by Respondents to the Waivered Physician Survey

### • *Physicians say the 30-Patient Limit Restricts Access to Treatment.*

- The 30 patient limit...has been a major problem limiting treatment. I constantly have a waiting list of 15-20. So do all the other waivered physicians in the area. This limit has to be removed to provide better access to care.
- It is a crime and unethical to continue to deny access to so many patients. Can you in good conscience not open up access to this life-saving treatment to thousands?
- We have been at 30 for months with only a 1 or 2 pt per month attrition rate. The demand is huge. We work with vulnerable populations (HIV, homeless, non-English speaking, chronic psych) and the referrals keep pouring in.

### • *Physicians are forced to change treatment practices.*

- I would like the patient to be able to continue maintenance BUP if possible, but there are not many physicians in the area to do so because of the 30 patient limit.
- I don't know any surgeons who limit appendectomies at 30! BUP is to my opioid addicts what SSRI's are to my depressed patients.
- I no longer can offer maintenance therapy thus resulting in high relapse rate. The limit is definitely adversely affecting patient care. The government is committing malpractice with limit. The health value of BUP greatly outweighs the risks of diversion.

### • *Physicians say it is not necessary.*

- Until BUP is treated like any other prescription with no additional constraints placed on doctors, both doctors and patients will continue to stigmatize this area of medical care.
- It is akin to placing limits on cardiac or diabetic patients. When are we truly going to acknowledge this problem as a disease and let those of us who practice addiction medicine full time do what we are trained for? It is unconscionable to turn patients away because of some bureaucratic limits.



# Organizational Perspectives on the 30 Patient Limit and Low Patient Demand

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- Prior to the change in law regarding group practices, physicians organized as large health care group practices were reluctant to provide BUP treatment due to the resources required to track the number of BUP patients treated simultaneously among members of the group.
- Due to the 30 patient limit on individual physicians, managed care network managers have reported difficulty finding physicians with open treatment slots. They have also reported encountering physician preference for detox instead of maintenance.
- Tracking Study respondents reported patient and physician demand for BUP treatment in the third-party payment system was low but increasing.

# Summary of Issues & Challenges

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- Top challenges to providing BUP treatment under the Waiver Program include:
  - Cost of BUP medication
  - Concerns about the logistics of induction
  - 30 patient limit
  - Low patient demand in some areas
- Other challenges that were rarely endorsed included:
  - Risk of diversion
  - Concern about adverse reactions

# Some Conclusions

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- BUP treatment under the Waiver Program appears to be clinically effective and is well accepted by patients.
- The Waiver Program appears to have increased the availability of medication-assisted treatment for opioid addiction.
- Adverse effects, whether involving diversion or adverse clinical events or public health consequences, have been minimal.
- The 30-patient limit on individual physician practices and cost / reimbursement issues may be decreasing potential access to treatment.
- Longer term studies are necessary to determine the relative cost-effectiveness of BUP treatment under the Waiver Program.

# Coming Up.....



Kissin, W., McLeod, C., Sonnefeld, J., & Stanton, A. (in press). Experiences of a national sample of qualified addictions specialists who have and have not prescribed buprenorphine for opioid dependence. *Journal of Addictive Diseases*.

# SAMHSA/CSAT Evaluation of the Buprenorphine Waiver Program: Contacts

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**For the original study overview and more information on buprenorphine, opioid treatment, and the Physician DATA Waiver Program, go to <http://buprenorphine.samhsa.gov>**