



## ***Modular Program Report***

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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## Overview

**Request Description** FDA requested the use of modular program #3 to investigate use of Bupropion and Naltrexone. The query was run against the Mini-Sentinel Distributed Database and distributed on October 26, 2011.

Results of MP #3 provide counts of prevalent users, dispensings, and total days supplied of Bupropion and Naltrexone, each independent of other drug use. Prevalent use was estimated with a drug washout period of zero days. The maximum allowable treatment gap was set to 14 days; the minimum episode duration and the minimum episode days supplied were set to 0 days. The program restricted the care setting to outpatient (AV) only. The output was stratified by three pre-existing condition groups, and the pre-existing condition lookback period was set to 90 days. Table 1 and Figure 1 display the results of MP3.

Please review the Notes below and refer to the Specifications table for request details.

**Request ID** MSY3\_MPR18

**Specifications** Program parameter inputs and scenarios

**Table 1** Number of users, dispensings, and days supplied for each pre-existing condition group by drug product, age group, sex, and index year

**Figure 1** Five figures depicting the number of users, dispensings, days supplied, days supplied per user, dispensings per user, and days per dispensing for each pre-existing condition group by drug product

**Appendix A** ICD-9-CM Codes and related descriptions for each pre-existing condition group

**Notes:** The program was run from January 1, 2005 to December 31, 2010. When examining the yearly stratification, note once an incident user is first encountered, this user will not be counted for subsequent years.

Please contact the Mini-Sentinel Operations Center ([MSOC\\_Requests@harvardpilgrim.org](mailto:MSOC_Requests@harvardpilgrim.org)) for questions and to provide comments/suggestions for future enhancements to this document.

**Modular Program Specifications**

Modular Program #3 was used to investigate the the number of prevalent users, dispensings, and total days supplied of Bupropion and Naltrexone by pre-existing condition. The query period was from January 1, 2005 to December 31, 2010, the enrollment gap was set at 45 days, and the maximum allowable treatment gap was set at 14 days. Age groups were split as follows: 0-17, 18-64, and 65+. In total, six different scenarios were examined in this report with differing incident exposures and pre-existing conditons. See below for a description of each of these scenarios.

Scenario	Drug/Exposure Criteria			Pre-Existing Condition Criteria			
	Incident exposure	Incident w/respect to:	Washout (days)	Pre-Existing Dx*	Lookback Period (days)	Care Setting	Principal Dx
1	Bupropion	Bupropion	0	Obesity	90	AV	NO
2	Bupropion	Bupropion	0	Drug Abuse	90	AV	NO
3	Bupropion	Bupropion	0	Psychiatric Disorder	90	AV	NO
4	Naltrexone	Naltrexone	0	Obesity	90	AV	NO
5	Naltrexone	Naltrexone	0	Drug Abuse	90	AV	NO
6	Naltrexone	Naltrexone	0	Psychiatric Disorder	90	AV	NO

\*Appendix A contains lists of diagnosis codes considered for each pre-existing condition group

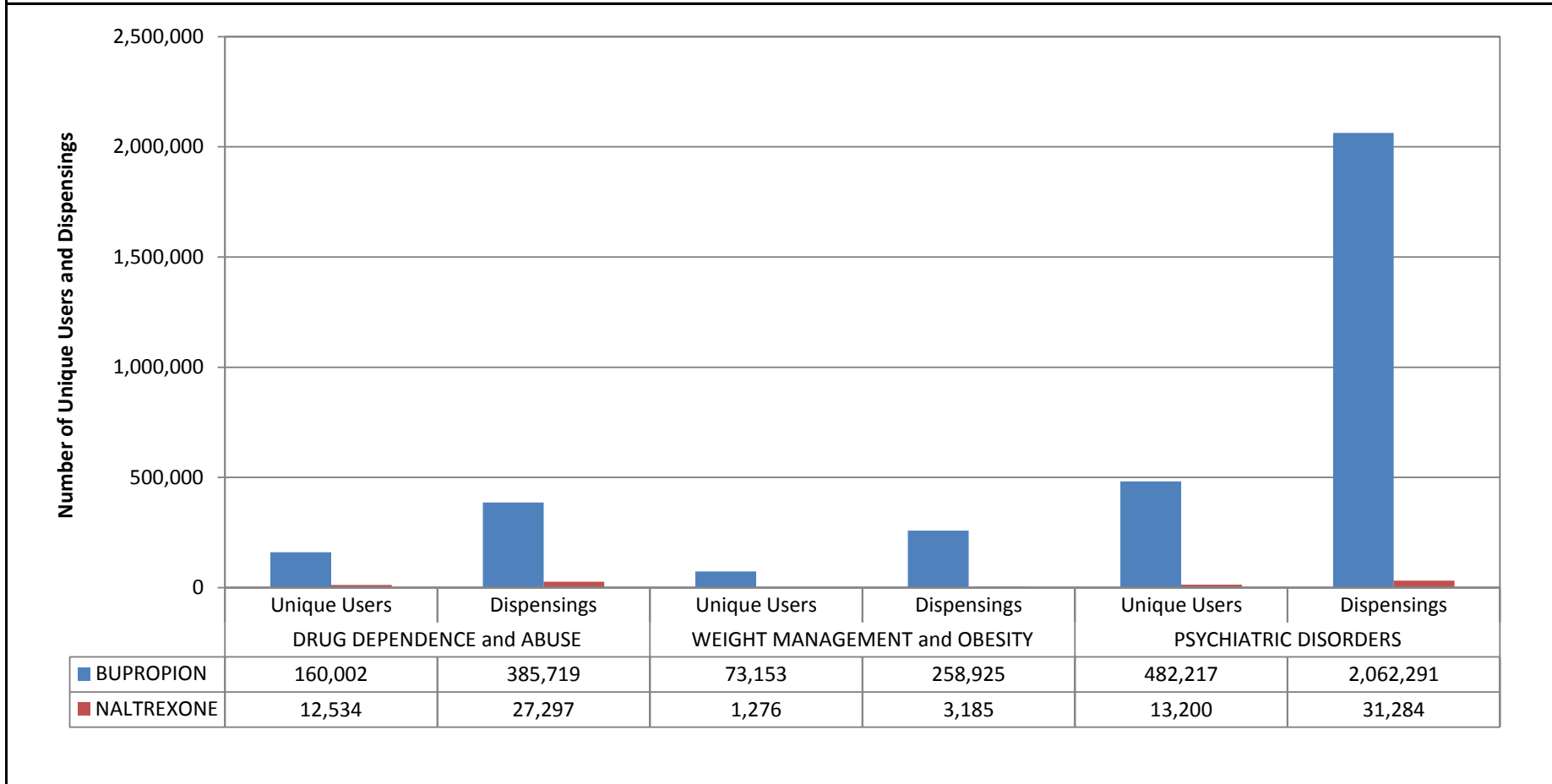


**Table 1. Unique Users, Dispensings, and Total Days Supplied by Drug Product Overall, Age Group, Sex, and Index Year for Each Pre-Existing Condition Group\***

		Pre-Existing Condition Group**									
		DRUG DEPENDENCE and ABUSE			WEIGHT MANAGEMENT and OBESITY			PSYCHIATRIC DISORDERS			
		Unique Users	Dispensings	Total Days Supplied	Unique Users	Dispensings	Total Days Supplied	Unique Users	Dispensings	Total Days Supplied	
BUPROPION	OVERALL	160,002	385,719	14,947,796	73,153	258,925	11,650,735	482,217	2,062,291	75,998,861	
	AGE GROUP	0 to 17	2,897	9,597	317,609	1,498	5,827	200,005	29,429	125,912	4,279,143
		18 to 64	144,800	348,286	13,410,432	66,303	233,968	10,382,348	422,981	1,810,370	66,310,382
		65+	12,305	27,836	1,219,755	5,352	19,130	1,068,382	29,807	126,009	5,409,336
	SEX	Ambiguous	.	.	.	.	.	.	2	5	430
		Female	86,621	213,036	8,306,933	53,624	193,318	8,510,398	311,244	1,338,746	49,397,456
		Male	73,287	172,466	6,634,333	19,474	65,374	3,133,047	170,379	721,202	26,529,356
		Unknown	94	217	6,530	55	233	7,290	592	2,338	71,619
	INDEX YEAR	2005	43,483	120,947	5,040,024	26,044	100,738	5,317,395	135,881	758,880	28,488,954
		2006	28,166	63,268	2,503,790	11,443	39,412	1,774,835	70,953	302,112	11,166,936
		2007	21,114	50,085	1,998,427	8,547	31,662	1,294,471	66,555	283,070	10,434,870
		2008	20,773	50,035	1,843,396	8,469	30,366	1,179,176	68,553	271,227	9,827,537
2009		25,058	57,694	2,026,990	9,633	32,655	1,206,668	73,128	257,989	9,321,624	
2010		21,408	43,690	1,535,169	9,017	24,092	878,190	67,147	189,013	6,758,940	
NALTREXONE	OVERALL	12,534	27,297	840,914	1,276	3,185	103,696	13,200	31,284	953,943	
	AGE GROUP	0 to 17	95	237	6,446	41	146	4,575	554	1,677	50,890
		18 to 64	12,050	26,052	798,311	1,184	2,914	94,204	12,306	28,668	871,169
		65+	389	1,008	36,157	51	125	4,917	340	939	31,884
	SEX	Ambiguous	.	.	.	.	.	.	.	.	.
		Female	5,442	11,954	368,046	893	2,263	72,862	6,749	16,248	492,435
		Male	7,077	15,306	472,011	382	921	30,804	6,431	14,974	459,835
		Unknown	15	37	857	1	1	30	20	62	1,673
	INDEX YEAR	2005	1,661	3,939	123,074	212	617	21,967	1,865	5,556	174,810
		2006	1,679	3,814	121,952	150	332	10,483	1,704	4,180	126,201
		2007	1,930	4,260	128,701	171	512	16,247	2,033	4,944	150,926
		2008	2,280	4,850	150,138	194	572	18,354	2,334	5,314	160,454
2009		2,522	5,607	168,566	237	562	17,961	2,667	6,107	183,262	
2010		2,462	4,827	148,483	312	590	18,684	2,597	5,183	158,290	

\*Bupropion users and Naltrexone users are independent of each other in these results  
 \*\*See Appendix A for ICD-9-CM codes and descriptions of pre-existing condition groups

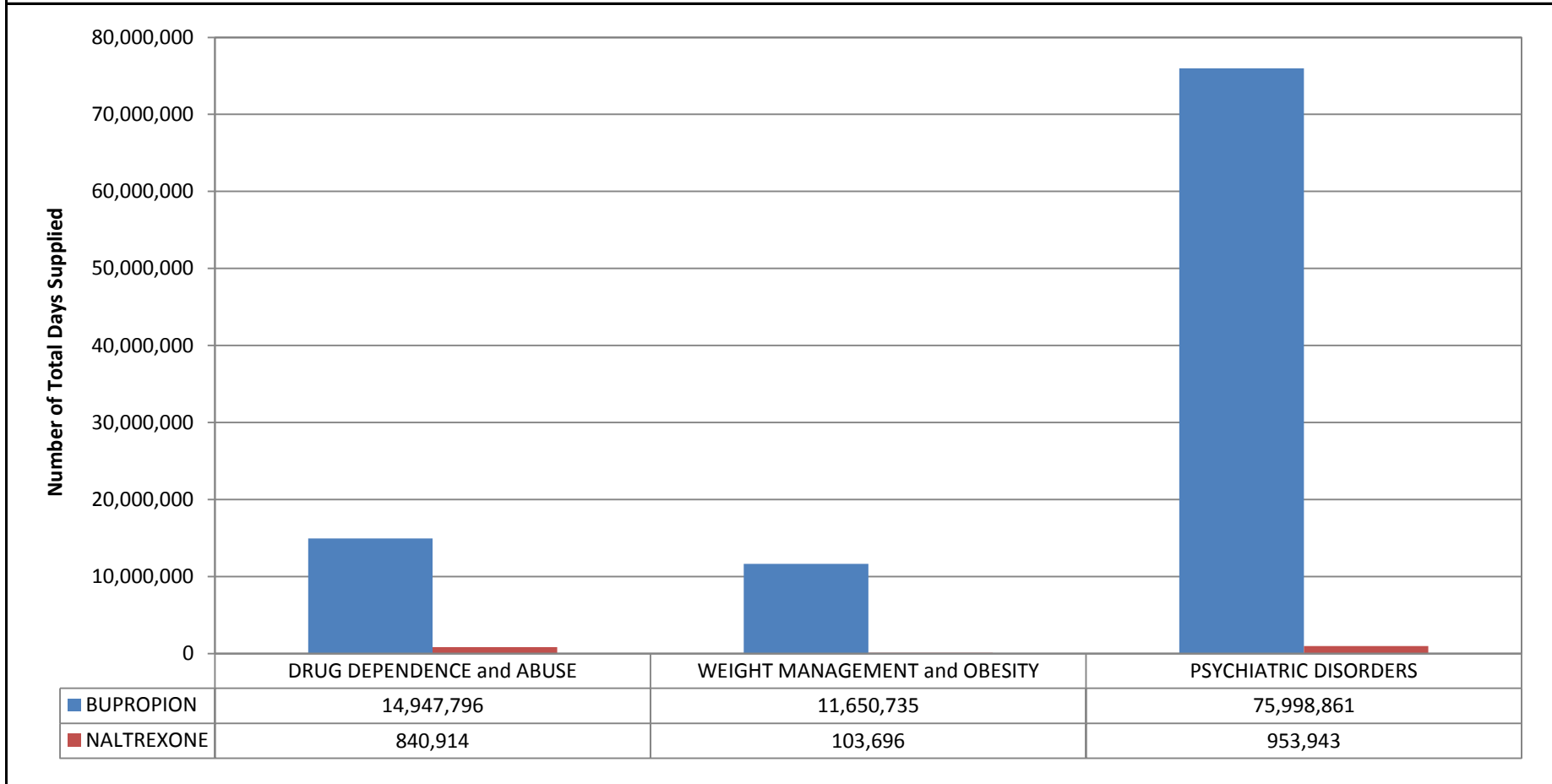
Figure 1a. Number of Unique Users and Dispensings by Drug Product\* and Pre-Existing Condition Group\*\*



\*Bupropion users and Naltrexone users are independent of each other in these results

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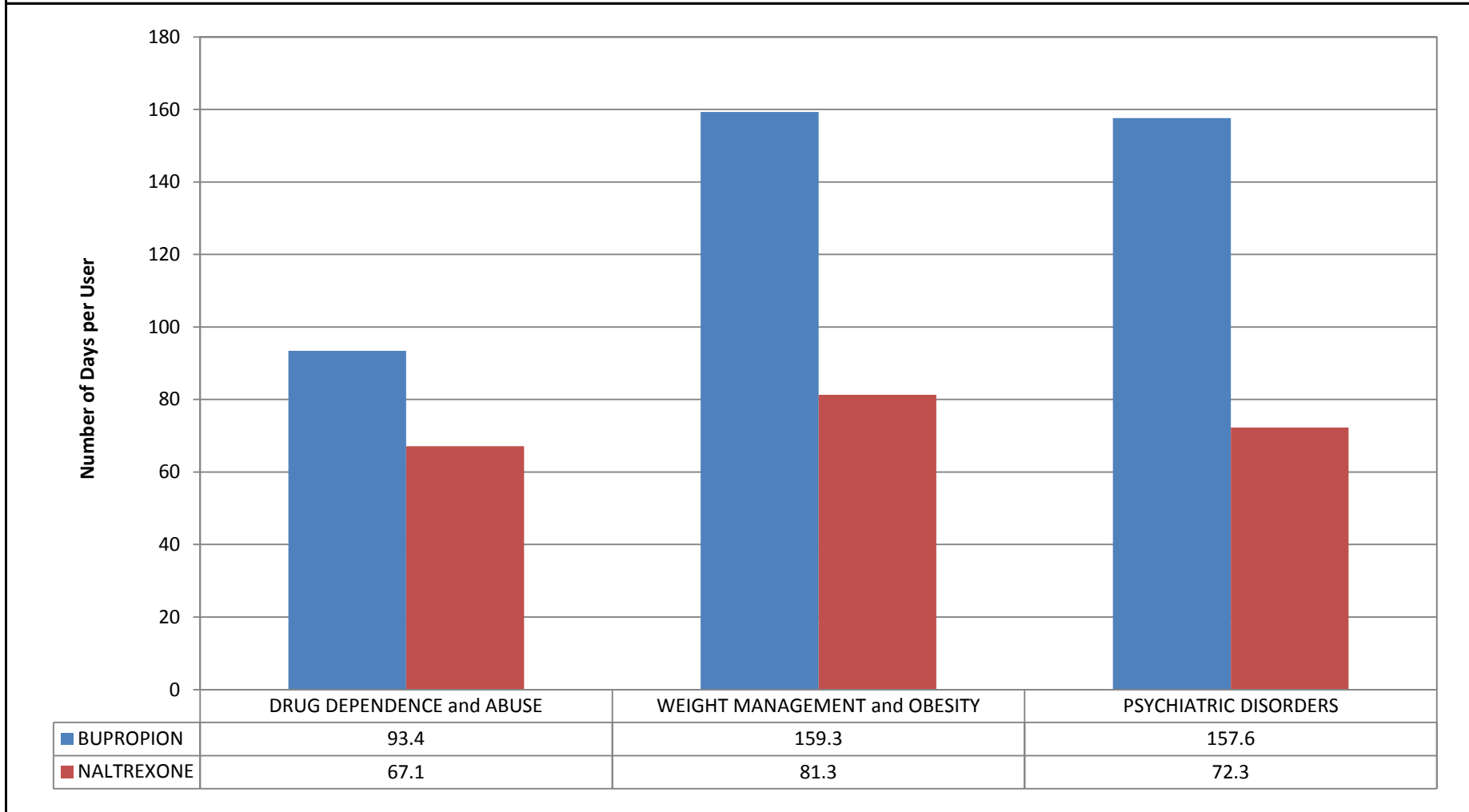
Figure 1b. Number of Total Days Supplied by Drug Product\* and Pre-Existing Condition Group\*\*



\*Bupropion users and Naltrexone users are independent of each other in these results

\*\*See Appendix A for ICD-9-CM codes and descriptions of pre-existing condition groups

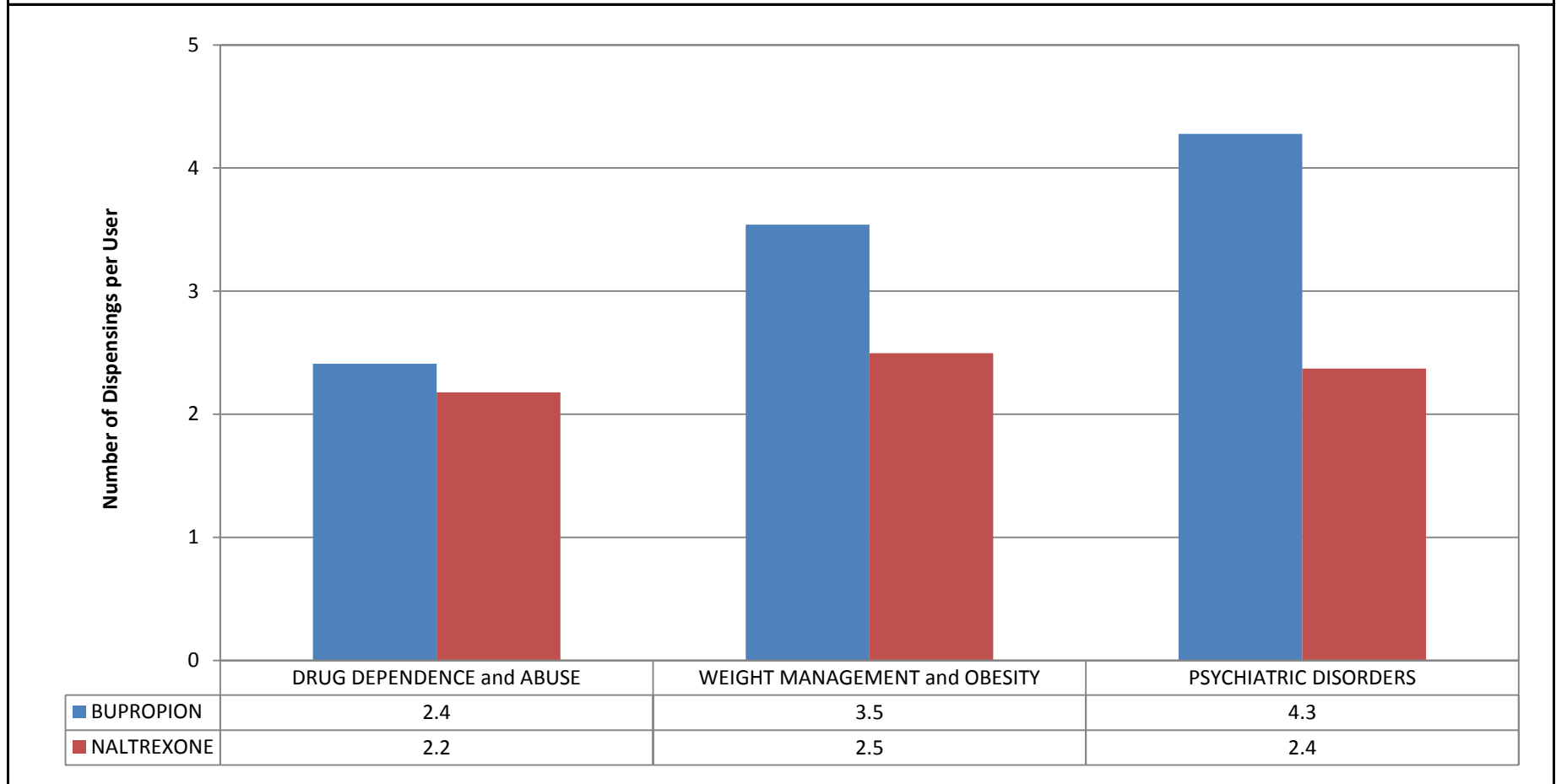
Figure 1c. Number of Days per User by Drug Product\* and Pre-Existing Condition Group\*\*



\*Bupropion users and Naltrexone users are independent of each other in these results

\*\*See Appendix A for ICD-9-CM codes and descriptions of pre-existing condition groups

Figure 1d. Number of Dispensings per User by Drug Product\* and Pre-Existing Condition Group\*\*

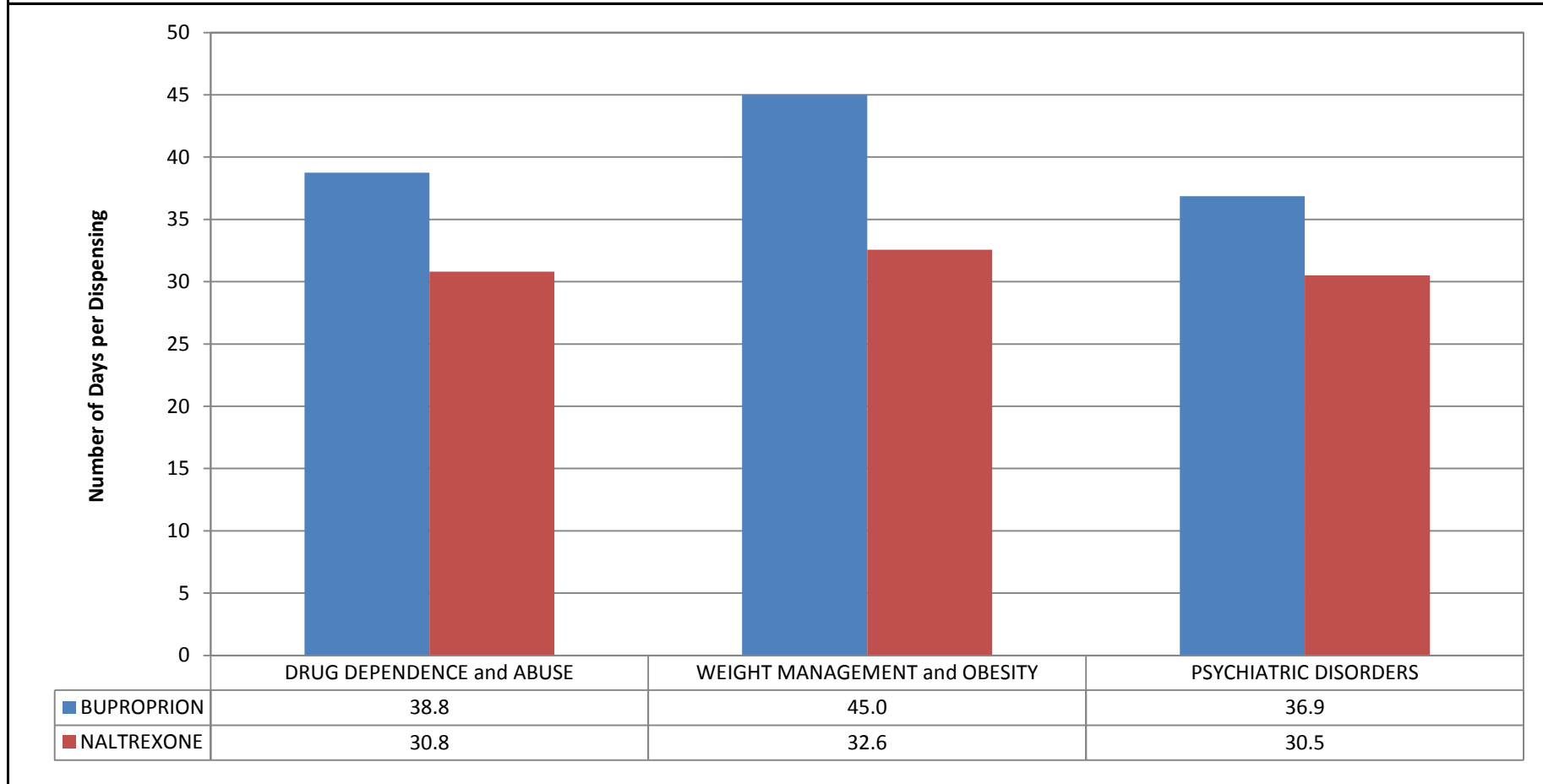


\*Bupropion users and Naltrexone users are independent of each other in these results

\*\*See Appendix A for ICD-9-CM codes and descriptions of pre-existing condition groups



Figure 1e. Number of Days per Dispensing by Drug Product\* and Pre-Existing Condition Group\*\*



\*Bupropion users and Naltrexone users are independent of each other in these results

\*\*See Appendix A for ICD-9-CM codes and descriptions of pre-existing condition groups

**Appendix A. ICD-9-CM Codes and Descriptions by Pre-Existing Diagnosis Group**

Psychiatric Disorders	Psychiatric Disorders cont.	Drug Dependence and Abuse cont.
290.2 SENILE DELUSION/DEPRESS 290.4 ARTERIOSCLEROT DEMENTIA 293.8 OTH TRANSIENT ORG MENTAL 294.1 DEMENTIA IN OTH DISEASES 294.9 UNS PERSIS MED DIS NOS 295.3 PARANOID SCHIZOPHRENIA 295.6 RESIDUAL SCHIZOPHRENIA 295.7 SCHIZOAFFECTIVE TYPE 295.8 SCHIZOPHRENIA NEC 295.9 SCHIZOPHRENIA NOS 296.0 MANIC DIS, SINGL EPISODE 296.1 MANIC, RECURRENT EPISODE 296.2 DEPR PSYCH, SINGL EPISOD 296.3 DEPR PSYCH, RECUR EPISOD 296.4 BIPOLAR AFFECTIVE, MANIC 296.5 BIPOLAR AFFECT, DEPRESS 296.6 BIPOLAR AFFECTIVE, MIXED 296.7 BIPOLAR AFFECTIVE NOS 296.8 MANIC-DEPRESSIVE NEC/NOS 296.9 AFFECT PSYCHOSES NEC/NOS 297.1 PARANOIA 298.9 PSYCHOSIS NOS 299.0 INFANTILE AUTISM 299.8 EARLY CHLD PSYCHOSES NEC 300.0 ANXIETY STATES 300.2 PHOBIC DISORDERS 300.3 OBSESSIVE-COMPULSIVE DIS 300.4 NEUROTIC DEPRESSION 300.5 NEURASTHENIA 300.9 NEUROTIC DISORDER NOS 301.0 PARANOID PERSONALITY 301.1 AFFECTIVE PERSONALITY 301.2 SCHIZOID PERSONALITY 301.4 COMPULSIVE PERSONALITY 301.7 ANTISOCIAL PERSONALITY 301.8 OTHER PERSONALITY DIS 301.9 PERSONALITY DISORDER NOS 302.7 PSYCHOSEXUAL DYSFUNCTION 302.9 PSYCHOSEXUAL DIS NOS 307.8 PSYCHALGIA 308.0 STRESS REACT, EMOTIONAL 308.1 STRESS REACTION, FUGUE	308.9 ACUTE STRESS REACT NOS 309.0 BRIEF DEPRESSIVE REACT 309.2 ADJUST REACT/OTH EMOTION 309.8 OTHER ADJUST REACTION 309.9 ADJUSTMENT REACTION NOS 311.0 DEPRESSIVE DISORDER NEC 312.3 IMPULSE CONTROL DIS NEC 312.9 CONDUCT DISTURBANCE NOS 313.3 RELATIONSHIP PROBLEMS 313.8 OTH EMOTIONAL DIS CHILD 314.0 ATTENTION DEFICIT DIS 314.1 HYPERKINET W DEVEL DELAY 315.2 OTH LEARNING DIFFICULTY 331.0 ALZHEIMER'S DISEASE 347.0 CATAPLEXY AND NARCOLEPSY 648.4 MENTAL DISORDERS IN PREG 780.0 ALTER OF CONSCIOUSNESS 780.5 SLEEP DISTURBANCES 799.2 NERVOUSNESS V119 HX-MENTAL DISORDER NOS V400 PROBLEMS WITH LEARNING V403 BEHAVIORAL PROBLEMS NEC V417 SEXUAL FUNCTION PROBLEM V628 OTH PSYCHOLOGICAL STRESS V652 PERSON FEIGNING ILLNESS V673 PSYCHIATRIC FOLLOW-UP	304.8 COMB DRUG DEPENDENCE NEC 304.9 DRUG DEPENDENCE NOS 305.0 ALCOHOL ABUSE 305.1 TOBACCO USE DISORDER 305.2 CANNABIS ABUSE 305.5 OPIOID ABUSE 305.6 COCAINE ABUSE 305.7 AMPHETAMINE ABUSE 305.9 DRUG ABUSE NEC/NOS
	<b>Weight Management and Obesity</b>	
	307.5 EATING DISORDERS NEC/NOS 278.0 OBESITY 783.1 ABNORMAL WEIGHT GAIN 783.0 ANOREXIA 307.1 ANOREXIA NERVOSA	
	<b>Drug Dependence and Abuse</b>	
	291.8 ALCOHOLIC PSYCHOSIS NEC 292.0 DRUG WITHDRAWAL SYNDROME 292.9 DRUG MENTAL DISORDER NOS 303.9 ALCOHOL DEPEND NEC/NOS 304.0 OPIOID TYPE DEPENDENCE 304.1 BARBITURATE DEPENDENCE 304.2 COCAINE DEPENDENCE 304.3 CANNABIS DEPENDENCE	