The Sell Effect: Involuntary Medication Treatment Is a "Clear and Convincing" Success

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> The Supreme Court ruling Sell v. United States in 2003 (539 U.S. 166) set a new precedent by mandating federal judges function as decision makers on the issue of whether "nondangerous" incompetent defendants charged with federal crimes can be involuntarily medicated to restore their competency to stand trial. To provide data to inform future opinions by mental health professionals and decisions for judges involved in these matters, a retrospective record review of all incompetent defendants in the entire U.S. federal court system (N = 132) involuntarily treated under *Sell* over a 6-year period was conducted. Results indicated the majority (79%) of treated defendants suffering from a psychotic related illness were sufficiently improved to be rendered competent to stand trial, surpassing the "clear and convincing" standard established by federal appellate courts. High rates of treatment responsiveness were found across all diagnoses.

Keywords: competence to stand trial, Sell v. U.S., competency restoration, involuntary medication

Mental health professionals who work with incompetent defendants should now be well aware of the U.S. Supreme Court decision in Sell v. United States (2003). In the Sell case, the court ruled that four criteria must be met before the government may override a "nondangerous," incompetent defendant's refusal of treatment with antipsychotic medication. First, it must be demonstrated that important governmental interests are at stake in bringing to trial an individual accused of a serious crime. Second, it must be shown that forced medication will significantly further government interests by being "substantially likely" to render the defendant competent to stand trial and substantially unlikely to have side effects that will interfere significantly with the defendant's ability to assist counsel in conducting a defense. Third, the court must conclude that involuntary medication is necessary to further those interests and find that alternative, less intrusive treatments are unlikely to achieve substantially the same results. And finally, the court must conclude that administering the drugs is medically appropriate.

As noted in the second criteria, the trial court must determine whether involuntary treatment will be "substantially likely" to restore the defendant's competency. "Substantially likely" and "substantially unlikely" are legal concepts that are not defined in

the narrative of the Sell decision. However, some legal guidance can be found in other judicial opinions. A 1999 Supreme Court decision in a class action lawsuit regarding settlement of claims against a manufacturer of asbestos-containing products (Ortiz v. Fibreboard Corporation, 1999) referenced a previous judicial definition of "substantial probability" as "less than a preponderance but more than a mere possibility." In the case United States v. Gomes (2002), the Second Circuit established the requirement for "clear and convincing evidence" as the appropriate legal standard on this issue. In this case, the Second Circuit was satisfied that expert witness testimony of an estimated 70% rate of success in restoring Mr. Gomes to competency met the standard of "clear and convincing evidence." This standard has been described by other appellate courts (see United States v. Bradley, 2005 and United States v. Rivera-Guerrero, 2004).

Unfortunately, there is limited empirical data on the results of involuntary psychiatric treatment of incompetent defendants and whether there is "clear and convincing" evidence that treatment effectively restores competency. Some studies peripherally address this issue, but limitations in each of the following studies warrant a closer examination of treatment in this context and the circumstances of a Sell request. One potential ambiguity in the involuntary treatment literature is whether the patient is involuntarily being confined to a psychiatric hospital but still able to voluntarily accept or refuse psychotropic medication or whether the patient is specifically being subjected to involuntary administration of antipsychotic medication.

In 1992, Nicholson and McNulty concluded that failure to restore defendants to competency was an infrequent event. The authors reviewed 150 cases from a state forensic hospital and found that in only eight (5.3%) of these cases did the treatment team recommend discharge of a patient after determining it was not possible to restore the defendant to competency. More than 40% of the sample included defendants not diagnosed with psy-

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chotic disorders. This is somewhat unusual, in that other published data indicates the majority of incompetent defendants suffer from schizophrenia or a related psychotic illness (Nicholson & Kugler, 1991; Pirelli, Gottdiener, & Zapf, 2011). Further, it was not clear what type of treatment was implemented, what percentage of defendants received antipsychotic medication, or whether treatment was on a voluntary or involuntary basis.

A 1993 article by Ladds, Convit, Zito, and Vitrai described the outcome of 61 New York state-indicted felony offenders in a 4.5-year period who were committed to a New York state hospital in order to be rendered competent to stand trial. All except two of the individuals had a primary diagnosis of a psychotic disorder, most of which were schizophrenia. Judges granted the request for involuntary treatment in 46 cases that had court hearings. Fifteen cases were omitted because the patient consented to treatment. Of the 46 cases that were involuntarily medicated, 93% were described as having an unequivocally good clinical response, the majority of which were described as rapid, robust and "dramatic." Forty-five cases completed an adequate trial of involuntary medication, with 39 cases (87%) being restored to competency to stand trial.

An article published in 2007 by Herbel and Stelmach described a group of 22 incompetent federal defendants diagnosed with delusional disorder who were involuntarily treated with antipsychotic medication for restoration of competency. The mental health evaluators in that study opined that 17 of these 22 defendants (77%) had improved sufficiently to be considered restored to competency status. This diagnostic group is frequently unrepresented in the literature and difficult to study, because most patients diagnosed with delusional disorder function relatively well outside their delusional beliefs and frequently do not come to the attention of mental health providers. Although this study's sample size was small, these authors were able to add to the limited literature on this population.

Mossman (2007) summarized a review of records of all inpatient pretrial defendants who underwent court-mandated treatment for competency restoration at an Ohio state psychiatric hospital between 1995 and 1999. During that period of time, 268 felony defendants were treated for competency restoration. In addition to medication treatment, the defendants were involved in group therapy and didactic sessions. The majority of these defendants (70%) were diagnosed with schizophrenia or another psychotic disorder. Of these felony defendants, 201 were restored to competency, resulting in an overall success rate of restoration of 75%.

In a recent study by Colwell and Gianesini (2011), conducted in a Connecticut state hospital, the authors examined variables that might predict nonrestorability of 71 criminal defendants who were court-ordered for restoration. Overall, 53 (75.7%) defendants were judicially deemed competent to stand trial following treatment. However, only 59% of those diagnosed with a psychotic disorder were restored. Many of them were involved in competency restoration classes, and nearly 75% were prescribed medications. The majority of patients complied with treatment, but eight (15.1%) were either administered medication involuntarily or not medicated at all.

The restoration results from these studies are generally consistent with published data on treatment effectiveness of antipsychotic medication for those diagnosed with schizophrenia and other psychotic disorders (e.g., Buchanan et al., 2009; Lehman et al., 2004). However, there is little scientific data as to whether administration of antipsychotic medication to nondangerous individuals on an *involuntary* basis for restoration purposes will result in similar outcomes (Incidentally, "nondangerous" refers to risk of danger toward self or others within the confines of custody, as described in the Supreme Court decision in *Sell v. United States*, 2003). Involuntary patients may differ in substantial ways from patients who consent to treatment. These could include differences in level of insight, course, severity of the illness, and motivation to improve, all of which could potentially impact the effectiveness of any treatment efforts.

This project is designed to address the limitations of the above studies and produce the first set of data ever published describing the rates of restoration of competency to stand trial for a large cohort of incompetent felony defendants who were *involuntarily* treated with antipsychotic medication under the *Sell* criteria. The main purpose of this study is to inform evaluators and courts as to the frequency with which defendants who are ordered to receive this type of involuntary treatment are restored to competency. Based on available data, the current authors hypothesized that psychotic defendants who undergo involuntary treatment and whom clinicians view as likely to respond favorably to treatment will improve sufficiently to be rendered competent to stand trial. Additionally, exploratory analyses will be conducted on the potential impact other variables (i.e., medication, route of administration, age, and race) may have on restoration likelihood.

Method

Procedures

The principle database for this project consists of all pretrial forensic evaluations within the entire U.S. Federal Court System, between June 2003 and December 2009. The evaluations of male defendants were conducted on an inpatient basis by licensed clinical psychologists and psychiatrists with several years of forensic experience. In only one case was involuntary treatment requested for a woman. This case was not included in the analyses. According to federal statute, the evaluation and treatment process took place over the course of, and up to, 4 months. Typical assessment procedures included numerous interviews, observations by staff members, review of extensive investigative materials and medical records, collateral interviews with family members, and psychological testing when appropriate. Cases in which defendants were considered incompetent to stand trial and involuntary treatment was requested and granted by the courts were included in the analyses. According to the Sell decision, clinicians requested involuntary treatment only after determining other forms of intervention would be unlikely to achieve substantially the same results as medication. Extracted data from the forensic reports included the following: age, race, charges, diagnoses, medication, opinion on competency restoration (clinician and ultimate judicial finding), and duration of treatment. Judicial determinations of competency status were retrieved from the Public Access to Court Electronic Records (PACER).

For the purposes of this study, involuntary treatment was defined as administration of oral or injectable antipsychotic medication occurring after a judicial hearing and court order specifically authorizing such medication be administered against the will of the defendant to treat his mental disorder in order to restore him to competency. Because Federal Bureau of Prisons policies are designed to limit the staff use of force, the actual implementation of involuntary medication under these circumstances is accomplished by the least amount of coercion possible. The preferred method is to persuade the defendant to comply with oral medication or accept long-acting injections of medication without resistance. Only after these interventions are unsuccessful is a Calculated Use of Physical Force scheduled. A calculated use of force is a security procedure performed by custody staff whereby the defendant is physically restrained, according to Bureau of Prisons policy, in order that administration of medication can be done in a safe and effective manner. Although data are unavailable as to the number of individuals requiring a use of force, from the authors' extensive experience, this is a very rare event and the few defendants who required a use of force subsequently complied with the prescribed medication regimen without further resistance.

For the past several years, approximately 350–400 federal felony defendants were admitted each year to prison psychiatric hospitals within the Bureau of Prisons for treatment to restore their competency to stand trial (P. Sahwell, personal communication, December 17, 2010). This pales in comparison to the number of defendants charged with a federal crime each year. For instance, according to the Federal Justice Statistics Program, there were more than 91,000 defendants in federal criminal cases in Fiscal Year, 2007 alone (United States Department of Justice. Bureau of Justice Statistics, 2011). Absent a finding

Table 1Descriptive Statistics

of dangerousness to self or others, these defendants had the legal right to accept or refuse the recommended treatment with psychotropic medication to restore their competency. Although group didactic education was also offered to the defendants, few availed themselves of this legal information prior to medication treatment. The overwhelming majority of these "refusers" could not be treated on alternative grounds discussed in the *Sell* decision (e.g., danger to self or others); therefore, the courts were notified and requests were made to treat these nondangerous individuals in order to restore their competency. A total of 287 requests were made to federal courts from throughout the United States during this 6-year time period. Of these 287 requests, courts authorized involuntary medication treatment in 133 cases (46%).

The focus of the current study was on the restoration attempts for the treated defendants. A breakdown of the primary diagnoses represented is listed in Table 1. The participants were male defendants referred to one of four Federal Medical Centers in the United States, each of which contains one or more inpatient psychiatric units. Every defendant in the country where a request was made to treat a defendant involuntarily under *Sell* from June 2003 through 2009 was included in the study. According to the *Sell* decision, requests for involuntary treatment were only made for defendants deemed "substantially likely" to be restored to competency.

Demographic data were extracted from the forensic reports generated by the evaluators. The mean age of the defendants

_	Entire sample $(N = 287)$	Sell denied $(n = 154)$	Sell granted ($n = 133$)	Statistical result	
Age ^a	39.49 (9.89)	39.83 (9.55)	39.10 (10.3)	t(285) = .63, ns	
Charges ^b					
Illegal re-entry	29.6 (85)	39.6 (61)	18.0 (24)	$\chi^2(3) = 18.95, p < .001^{\circ}$	
Violent	25.1 (72)	25.3 (39)	24.8 (33)		
Firearms	17.1 (49)	13.6 (21)	21.1 (28)		
Nonviolent	28.2 (81)	21.4 (33)	36.1 (48)		
Ethnicity ^b					
Caucasian/White	32.1 (92)	31.2 (48)	33.1 (44)	$\chi^2(3) = 18.41, p < .001$	
African-American/Black	28.6 (82)	20.1 (31)	38.3 (51)		
Latino	34.1 (98)	44.2 (68)	22.6 (30)		
Other or unknown	5.2 (15)	4.5 (7)	6.0 (8)		
Primary diagnosis ^b					
Schizophrenia	56.4 (162)	51.9 (80)	61.7 (82)		
Schizoaffective disorder ^d	13.9. (40)	11.7 (18)	16.5 (22)	$\chi^2(3) = 9.16$, ns	
Delusional disorder	15.3 (44)	18.8 (29)	11.3 (15)		
Psychotic disorder, NOS	14.3 (41)	17.5 (27)	10.5 (14)		
Comorbid diagnosis ^b			~ /		
Cognitive disorder	4.2 (12)	4.5 (7)	3.8 (5)	$\chi^2(1) = .74$, ns	
MR/borderline IQ	9	5	4		
Dementia	2	1	1		
Other	1	1	0		
Substance disorder	(not coded)	(not coded)	33.1 (44)		
Alcohol			8		
Drugs			15		
Polysubstance			21		

Note. NOS = Not Otherwise Specified.

^a Values are means with standard deviation in parentheses. ^b Values are frequency, given as a percentage of sample with number of subjects in parentheses. ^c Boldface values indicate statistical significance. ^d Includes defendants identified with bipolar disorder (n = 8, 5, and 3, respectively) and depressive disorder with psychotic features (n = 4, 1, and 3, respectively).

was 39. Thirty-two percent of the defendants were Caucasian, 29% African American, 34% Latino, and 5% of another race.

Data Analysis Strategy

Independent samples *t* tests and nonparametric comparisons were used to examine if defendants judicially authorized to undergo involuntary treatment to restore competency differed from those not so-authorized. (The significance [p < .05] of bivariate associations of study variables with key constructs of interest [i.e., restorability, time to restoration] was assessed to determine if the variable should be included as a covariate in the planned regression analyses. We also examined the impact of methodological variables on the results [e.g., the number of days from the date *Sell* was granted to the date treatment was initiated].)

In order to evaluate the effectiveness of involuntary treatment, we first examined whether the proportion of those deemed restored to competency differed across meaningful groups of patients or by types of treatment provided. Next, a stepwise hierarchical logistic regression analysis was applied to determine if any of the study variables predicted restorability, using clinician ratings of competency as the dependent variable (1 = restored; 0 = not restored). The total duration of treatment (i.e., estimated by the number of days between date of admission post-Sell decision or initiation of treatment and date of final clinician report) was statistically controlled by entering this variable into Step one of the regression equation. In that regard, inclusion of age in the analyses was deemed important insofar as it serves as proxy for duration of illness, which may be related to illness severity as well as prior treatment exposure. Other key constructs of interest included demographic variables (e.g., race), diagnostic variables (i.e., type of psychotic condition, presence of comorbid cognitive disorder, and presence of comorbid substance disorder), and treatment variables (i.e., atypical vs. typical antipsychotic, oral vs. intramuscular administration). Only those variables entering into the equation via forward conditional stepwise regression (p < .05 to enter, .15 to remove) would be retained in the final model. Assessment of the significance of coefficients of the independent variables was pursued only if the overall model effect was significant.

Using tables provided by Cohen (1992), 107 participants were needed to detect a medium effect size (ES = 0.15) at an alpha of .05 with up to eight partially correlated "predictor" variables. The current sample of involuntarily treated defendants (N = 132) provided more than 90% power to detect the significance of the overall model and more than 80% power to detect the significance of the change in effect size attributable to the addition of up to 11 individual predictors over and above the effect of the planned covariate.

Results

Preliminary Analyses

Data entry checks were performed on a random subset of 30 cases (approximately 10%) for each of the coded variables. Next, the distributions of all variables were examined for possible violations of the assumptions of the planned analyses. Univariate outliers were identified and reined in by substituting the original values with the median \pm two interquartile ranges (Tabachnick &

Fidel, 2001). A total of 33 univariate outliers (two for age; 10 for interim between *Sell* decision and initiation of treatment; and, 21 for duration of restoration period) were identified by the medianinterquartile method. After applying those corrections, variable distributions were evaluated for violations of the assumptions of normality, linearity, and/or homoscedasticity via review of the skewness/kurtosis statistics and for tests of normality (i.e., Kolmogorov–Smirnov). Only the duration of treatment variable remained moderately skewed and thus, was subjected to a square root transformation. Analyses were performed using the transformed variable. The presence of multivariate outliers and collinearity statistics were also examined.

Additionally, several categories within selected coded variables contained too few cases for meaningful analyses (e.g., six cases of theft, five cases of property destruction) and consequently were regrouped to ensure a minimum number of 20 cases within each category. More specifically, the 14 original categories for legal charges were examined by retaining the two largest groups (Illegal Reentry and Firearms) and reclassifying the remaining cases as either Violent or Nonviolent Offenses. In post hoc analyses, we examined alternative groupings of charges (e.g., Illegal Re-entry vs. Other and Violent vs. Nonviolent); however, the results were not meaningfully different. In cases of multiple offenses (n = 8), the most serious offense was recorded; in cases of supervised release violation (n = 13), the original offense was recorded. In regard to diagnosis, there were just eight defendants with bipolar disorder, among whom three underwent involuntary treatment under Sell, and four defendants with a depressive disorder with psychotic features, among whom three underwent involuntary treatment; those cases were analyzed together with the schizoaffective disorder group for the planned regression analyses, because in each case the psychotic symptoms were accompanied by a significant mood component. Only a small minority of defendants were diagnosed with a comorbid condition involving cognitive impairment (n = 12), thus rendering analysis of individual categories (i.e., mental retardation, dementia) of limited utility.

In the present study, the last antipsychotic medication used was examined as either a first generation (n = 64) or a second generation (n = 68) antipsychotic. We also considered the route of administration as either intramuscular only (n = 72; 54.5%) or oral (n = 60; 45.5%). The majority of cases were treated with antipsychotic monotherapy with haloperidol being by far the most commonly used medication (Table 2).

Only 22 defendants were prescribed two or more psychotropic medications simultaneously during efforts to restore competency.

Table 2			
Medications	Utilized for	Competency	Restoration

Type of medication	n	Percentage of sample
Haloperidol	54	41.0
Risperidone	36	27.2
Aripiprazole	17	12.9
Fluphenazine	10	7.6
Ziprasidone	6	4.5
Olanzapine	6	4.5
Quetiapine	2	1.5
Clozapine	1	0.8

Note. n = 132 treated defendants.

Of this subgroup, there were 13 defendants with schizophrenia, seven with schizoaffective disorder, and one each of psychotic disorder not otherwise specified and bipolar disorder. Most frequently, antidepressant medicine was added to target depressive symptoms emerging after the initiation of involuntary treatment with antipsychotic medication, which occurred for seven defendants. One defendant was prescribed an antidepressant and a benzodiazepine to treat panic attacks that emerged after being involuntarily treated with antipsychotic medicine. In two defendants, prominent residual psychotic symptoms resulted in addition of a second antipsychotic medication. Mood stabilizing medicine was added to the antipsychotic regimen of three defendants to treat irritability or hypomania. A sedating antidepressant was added to the antipsychotic regimen of one defendant to target insomnia. Three patients were treated with two antipsychotic medications simultaneously from the beginning of involuntary treatment. The rationale for one of these cases was to continue a low dose of a long-acting injectable medication in case the defendant stopped taking the oral medicine. The rationale for the other two cases for initiating simultaneous treatment with two antipsychotics was not described. The remainder of these cases had mood-stabilizing or antidepressant medication added for reasons that were not described in the report.

Interestingly, five of the six defendants with a primary affective disorder were restored to competency following involuntary treatment with antipsychotic medication alone. The three cases of major depressive disorder with psychotic features were treated with either haloperidol, risperidone, or ziprasidone monotherapy. Two cases of bipolar disorder were restored to competency status on risperidone or fluphenazine monotherapy, with the third case requiring treatment with risperidone, lithium, and the tricyclic antidepressant amitriptyline for successful restoration.

Overall, the medication treatment was well tolerated. Minor complaints such as sedation, restlessness, and muscle stiffness were easily managed through a dose adjustment, switch to a different antipsychotic medicine, or use of adjunctive medicines. About a third of the cohort was prescribed adjunctive anticholinergic or beta blocker medicine at the end of the treatment period to manage neuromuscular side effects. One individual was described as feigning neuromuscular side effects in an unsuccessful effort to have the medicine discontinued. New-onset tardive dyskinesia was quite rare, with only one case being identified. This defendant developed new onset oral tardive dyskinesia following treatment with haloperidol decanoate, which improved somewhat after a medication switch to long-acting risperidone.

There were no cases of tardive dystonia, neuroleptic malignant syndrome, or unexpected sudden cardiac death. No suicides occurred in the cohort, with several individuals accepting treatment with antidepressant medicine for new onset depressive symptoms. Several individuals had improved health status after being involuntarily medicated, accepting treatment previously refused for chronic medical ailments such as HIV or hyperlipidemia.

Regarding metabolic side effects, one defendant developed new onset diabetes and elevated serum lipids following treatment with risperidone, but he refused to comply with recommendations for lifestyle modifications regarding dietary choices and exercise. His diabetes and elevated lipids persisted despite a switch from risperidone to aripiprazole, requiring treatment with insulin, metformin tablets, and a statin drug. Another defendant had no side effects during a trial of aripiprazole, but developed new onset diabetes following treatment with olanzapine. The diabetes improved after olanzapine was discontinued to the extent he did not require ongoing medical treatment. His diabetes did not recur during subsequent trials of ziprasidone and haloperidol. Significant weight gain was infrequent, with two patients gaining approximately 30 pounds and one gaining 20 pounds. The importance of nonpharmacological interventions in managing metabolic effects was demonstrated by two defendants, who manifested marked improvement in their baseline elevated serum lipids without lipidlowering medication despite ongoing treatment with antipsychotic medication, which was attributed to lifestyle modifications of dietary restriction and exercise. One had been treated with risperidone throughout the evaluation, with the other defendant initially administered haloperidol for 2 months, which was then switched to aripiprazole due to complaints of sedation.

Two deaths occurred in the cohort undergoing involuntary treatment, both in individuals with schizophrenia. One defendant in his 30s developed Wegener's granulomatosis, an extremely rare autoimmune disorder with an annual incidence in one study of 9.8 cases per million (Mohammad, Jacobson, Westman, Sturfelt, & Segelmar, 2009). This occurred after 3 months of treatment with olanzapine monotherapy, which had been preceded by an unspecified period of treatment with combination olanzapine and carbamazepine. He required medical hospitalization and hemodialysis for acute renal failure. The olanzapine was discontinued, although it was unclear whether this medicine was the etiology of the autoimmune disorder. After recovering on a medical floor during the next several weeks, he developed pneumonia and died despite medical interventions. The cause of death at autopsy was attributed to pneumonia as a complication of acute renal failure and crescentic glomerulonephritis. The second death involved a man in his 50s who had a history of multiple medical problems including hypertension, hyperlipidemia, type II diabetes, congestive heart failure, seizure disorder, and a previous stroke. During his lengthy pretrial detention he was consistently noncompliant with the recommended treatment of his multiple medical ailments because of beliefs of being miraculously healed. His congestive heart failure had worsened after he returned to FMC Butner for involuntary treatment 1 year after the initial evaluation, reflected by new-onset bilateral lower leg edema. Despite partial improvement in his psychotic symptoms following treatment with haloperidol, he remained nonadherent with most of the recommended medical interventions. His cardiovascular health status slowly and steadily deteriorated over the next several months, until his death. The cause of death at autopsy was attributed to ischemic heart disease, with findings of severe coronary artery disease with advanced dilated cardiomyopathy. Review of the data underlying these two deaths indicated one was unforeseeable, and the other might have been prevented if involuntary psychiatric treatment had been initiated prior to progression of his underlying cardiovascular disease.

Sample Characteristics

Table 1 presents the demographic and clinical characteristics of the entire sample of *Sell* requests (N = 287), 133 of which were granted (132 were ultimately treated).

Small but statistically significant racial disparities in Court authorization emerged, which were not present in the treatment outcomes of the cohort that was involuntarily medicated. Specifically, those ordered to undergo involuntary treatment were more likely to be Black/African American, $\chi^2(1) = 11.60$, p < .001, OR = 2.47, 95% CI = [1.46, 4.18], and less likely to be Latino, $\chi^{2}(1) = 14.81, p < .001, OR = 0.37, 95\% CI = [0.22, 0.62].$ Relatedly, requests for treatment of defendants charged with illegal reentry were less likely to be granted than were requests for defendants charged with other offenses, $\chi^2(1) = 15.92$, p < .001, OR = 0.34,95% CI = [0.19, 0.58]. Because there was a significant overlap between the Latino group and cases of illegal re-entry (nonparametric r = .85, p < .001), post hoc logistic regression analyses were conducted to test the potential meditational influence of charges on the observed racial difference. This analysis revealed that when variance attributable to legal charges was statistically controlled, B = -1.09, SE = 0.28; EXP(B) = 0.34, 95% CI = [0.19, 0.58]; Wald = 15.28, p < .001], the observed association between Latino race and Sell authorization, B = -0.95, SE = 0.56; EXP(B) = 0.39, 95% CI = [0.13, 1.16]; Wald = 2.87, p = .09, was significantly reduced, B = -0.38, *SE* = 0.68, EXP(B) = 0.69, 95% CI = 1.81, 2.60; Wald = 0.31, ns. In other respects, the groups of defendants were found to be statistically comparable.

Restorability

Reliability/validity of competency restoration opinions. Although certainly not independent determinations, the correspondence between clinician and judicial opinions of competency restoration for each defendant was evaluated by (a) percent agreement and (b) the Kappa statistic, which measures the pairwise agreement among raters making categorical judgments, correcting for expected chance agreement (Carletta, 1996).

A total of 133 defendants of the original sample were Court ordered to undergo involuntary treatment; however, one subsequently filed an appeal that has yet to be resolved. Clinician opinions of competency restoration were available for the remaining 132 cases. Of these, seven cases were dismissed before a competency hearing was held and in two others, no judicial findings were cited in the referenced court documents. Two defendants expired prior to judicial decision concerning competency.

In the remaining 121 cases, there was 96.7% agreement between clinician and judicial opinions of competency. Correspondence between restoration opinions remained excellent even after controlling for chance agreement (Cohen's $\kappa = .889$). In order to maximize statistical power, only clinician ratings of restoration were used for the planned analyses.

Frequently, reasons were not provided or could not be located in PACER for why the request for involuntary treatment was denied. However, in those cases for which courts articulated their reasoning (n = 28), 54% found that the prosecution did not have an important enough governmental interest (i.e., a minor criminal charge). In 32% of the cases, the courts concluded the government did not meet the threshold for one of the remaining three prongs of the test (i.e., treatment effectiveness, side effects, or medical appropriateness), and in 14% of the cases, the courts indicated the criteria were not met for both prongs one and at least one other "treatment" prong.

Restoration analyses. A substantial majority (n = 104; 78.8%) of the 132 defendants were viewed by clinicians as having been restored to competency following treatment. The type of charge was irrelevant to restoration, $\chi^2(3) = 2.60$, *ns.* In keeping with the results of the logistic regression analysis, the rate of improvement did not vary as a function of primary diagnosis $\chi^2(3) = 0.74$, *ns* or comorbid condition [Cognitive Disorder, $\chi^2(1) = 0.01$, *ns*, and Substance Disorder, and $\chi^2(1) = 1.45$, *ns*, respectively]. See Table 3.

In terms of treatment, 84.4% of those administered firstgeneration antipsychotic medications were restored to competency compared to 73.5% of those given second-generation antipsychotic medications; however, this difference did not reach statistical significance, $\chi^2(1) = 2.32$, p = .12, OR = 1.94, 95% CI [0.82,

Table 3		
Logistic	Regression	Analyses

	B(SE)	Exp(B); 95% CI	Wald
Step 3 $\Delta \chi^2(3) = 3.56$, ns			
Treatment duration	01 (.004)	.99 (.98, 1.00)	10.09, p < .001
Age	01 (.03)	.99 (.94, 1.04)	0, ns
Race $(1)^a$	01(1.20)	.99 (.08, 10.92)	0, ns
Race (2)	19 (1.20)	.83 (.08, 8.62)	.03, ns
Race (3)	-1.15 (1.21)	.32 (.03, 3.34)	.05, ns
Primary Dx (1) ^b	1.68 (1.19)	5.35 (.52, 54.64)	2.00, ns
Primary Dx (2)	1.27 (1.32)	3.56 (.27, 46.86)	.93, ns
Primary Dx (3)	1.64 (1.34)	5.17 (.37, 71.72)	1.45, ns
First generation vs. second generation	.58 (.63)	1.79 (.52, 6.14)	.85, ns
Route of administration	20 (.62)	.82 (.24, 2.78)	.10, ns
Step 4 $\Delta \chi^2(2) = .91$, ns			
Overall model $\chi^2(10) = 20.57, p < .05$			

Note. Boldface indicates statistical significance. Dx = diagnosis.

^a The four race classifications were dummy-coded into three variables, representing either White, Black, or Latino versus all other groups. ^b The three diagnostic groups in the table represent the four initial diagnoses that were dummy coded. The same is true for Race. The four primary diagnostic classifications were dummy-coded into three variables representing either schizophrenia, schizoaffective, or delusional disorder versus all other groups.

4.61]. There were also no differences in restoration between defendants who took medication orally (76.7%) and those requiring an injection (80.6%), $\chi^2(1) = .30$, *ns*, OR = 1.26, 95% CI [0.55, 2.91].

The results of the planned hierarchical logistic regression analyses revealed that with each increase in the duration of the treatment period there was a slightly reduced odds (0.99 times) the defendant would be restored to competency. After controlling for the influence of treatment duration, none of the remaining variables (age, race, primary diagnosis, drug type, and route of administration) were selected by the forward conditional stepwise regression as predictors of restorability (See Table 3).

Post Hoc Analyses—Treatment Duration

In the current sample, defendants underwent treatment for an average of 144.41 days (SD = 66.82; Median = 126); however, a few were restored to competency in less than a month, and others required a year or more (M = 133.2 days, SD = 62.76; Median = 120 days; Range = 20, 396 days). It was therefore of some interest to determine what, if any, variables predicted the amount of time required for successful restoration. In order to examine this question, we conducted a stepwise hierarchical regression analysis with the subset of defendants deemed restored to competency. Only the defendant's age entered as a significant predictor of treatment duration, such that increasing age was associated with a decreased duration of treatment, $\beta = -0.28$, 95% CI [-0.278, -0.55], t(1) = -2.59, p < .01; Model $R^2 = 0.08$, F(1) = 8.76, p < .01. In other words, results indicate the older the defendant, the shorter the amount of time necessary to restore him to competency.

Discussion

Treatment Effectiveness

For several decades, the use of antipsychotic medications to treat patients diagnosed with psychotic spectrum disorders, such as schizophrenia, has been reported as widely effective. The high treatment response rates found in this study are consistent with that published literature, including community based double-blind, randomized placebo-controlled studies of schizophrenia (e.g., Buchanan et al., 2009), as well as voluntary and involuntary treatment of pretrial defendants for restoration of competency (Ladds et al., 1993; Mossman, 2007; Nicholson & McNulty, 1992). The degree of treatment success across those studies has varied to some degree, depending on the drug used, the setting, and the patient population. This study examined whether treatment of mentally ill criminal defendants with antipsychotic medication on an involuntary basis under Sell would yield sufficiently positive results to restore their competency to stand trial. Following a judicial hearing and authorization to treat these federal criminal defendants, the majority (79%) demonstrated significant improvement and were considered to be restored to competency. These positive results were found across each of the diagnostic categories (i.e., schizophrenia, schizoaffective disorder, delusional disorder, and psychotic disorder Not Otherwise Specified; Table 4.

The consistently high response rate to antipsychotic medication treatment in defendants with various psychiatric diagnoses was remarkable. No differences in restoration outcome were found

Table 4			
Restoration	by	Diagnosis	

Diagnosis	Percentage restored (n)	
Schizophrenia ^a	76.5 (62 of 81)	
Schizoaffective ^b	81.8 (18 of 22)	
Delusional disorder	73.3 (11 of 15)	
Psychotic NOS	92.9 (13 of 14)	
Any cognitive disorder	80.0 (4 of 5)	
Any substance disorder	72.7 (32 of 44)	

Note. NOS = Not Otherwise Specified.

^a Total N = 81. ^b Includes those diagnosed with a primary mood disorder with psychotic features (n = 3 of 3 bipolar, 3 of 3 unipolar) who were successfully restored.

when some key variables were examined, such as diagnosis, age, race, type of criminal charge, type of medication, and route of medication administration. Notably, approximately 40% of this cohort could be considered treated in an off-label manner with antipsychotic medication, because most antipsychotic medications have been labeled by the Food and Drug Association (FDA) only for the treatment of schizophrenia (56.4% of cohort) and, to a lesser extent, bipolar disorder or major depressive disorder (4% of cohort). Despite legitimate concerns about possible inappropriate off-label prescribing practices in various branches of medicine, off-label prescribing in psychiatry is not only common and legally permissible, but has also been described as both ethical and necessary (Dresser & Frader, 2009; Ghaemi & Goodwin, 2007; Largent, Miller, & Pearson, 2009). These data demonstrates that off-label use of antipsychotic medication can be both safe and effective in restoring the competency of defendants diagnosed with delusional disorder, schizoaffective disorder, and psychotic disorder not otherwise specified.

The primary clinical outcome measure of the study, restoration of competency, was verified by judicial review. Judicial findings on competency restoration agreed with clinicians' opinions in 96% of the cases. Although judicial determinations are influenced by clinician opinion, this level of agreement is analogous to agreement found in other forensic situations. For instance, several studies in different jurisdictions have found agreement rates between clinicians and courts above 90% in competency to stand trial matters (Hart & Hare, 1992; Reich & Tookey, 1986; Williams & Miller, 1981). It is possible, as some have suggested (Zapf, Hubbard, Cooper, Wheeles, & Ronan, 2004), that judges may simply abdicate their decision-making role and defer to clinicians' judgment, making their rulings anything but independent. Independent review (e.g., a "blue ribbon panel of experts") may serve as a preferred criterion, but the lack of a "gold standard" remains problematic for competency restoration research. This study was limited to using clinician and judicial determinations as the only criterion to determine restoration outcome.

One other potentially interesting finding was that it took less time for symptom relief and competency restoration for older versus younger defendants. This is counterintuitive, because it would seem that older patients would more likely suffer from a more chronic and severe form of psychotic illness and would therefore be expected to have a slower treatment response. It is possible that the older defendants in the treatment cohort had a more recent acute-onset type of psychotic disorder or had more complete histories of past medication treatment responses to guide current effective treatment interventions. Unfortunately there was insufficient data in this study to confirm or refute these possibilities. At the minimum, the advancing age of defendants as a proxy for severity and chronicity of psychotic illness was not associated with a decreased response to medication treatment. Future studies will be necessary to replicate and discern the meaning of this data.

Frequency of Involuntary Treatment

In *Sell v United States* (2003), the Supreme Court noted the instances of involuntary administration of medication solely to restore trial competency "may be rare" because of the standards imposed on the government. This prediction was consistent with the findings of the present study. Of roughly 90,000 criminal defendants processed through the federal court system each year, approximately 350–400 are admitted each year to federal prison hospitals for competency restoration treatment. Of these, only 287 requests for involuntary treatment were made over a 6-year period of time (approximately 60 per year). Of those requests, involuntary treatment was granted in 133 cases (or about 25 per year). Therefore, the estimated rate of involuntary treatment of a federal defendant entering the criminal judicial system is approximately 1 in every 3,600 cases.

Nature of Involuntary Treatment

Involuntary psychiatric treatment obviously requires coercion, a complex phenomenon almost always perceived by the person undergoing it as a negative experience, which could theoretically result in adverse outcomes. However, research data indicates there are many outcomes from coercion. There is no strong quantitative evidence that the experience of coercion is negatively or positively associated with psychopathology or general well being. Some patients retrospectively have acknowledged coercion as a necessary intervention for them (Newton-Howes & Mullen, 2011). For example, 46% to 86% of a cohort of 2,326 involuntarily hospitalized patients felt their admission "was right" 3 months after discharge (Priebe et al., 2010). The favorable responses to treatment manifested in the current study indicate coercion within the context of *Sell* proceedings was not necessarily associated with adverse outcome.

In the present study, use of long-acting injections of antipsychotic medication compared to use of oral medication could be considered as a proxy for lack of insight and increased level of coercion. That is, those defendants who were not willing to cooperate with ingesting daily oral doses of antipsychotic medication were by default treated over their objection with injections of antipsychotic medication every 2 to 4 weeks. However, when defendants treated with injections were compared to those who complied with oral medication, no significant differences in restoration rates were found. This demonstrates the beneficial effects of antipsychotic medicine in treating incompetent defendants with active psychosis is not dependent on the route of administration, the degree of insight of the defendant, or the presence or absence of higher levels of coercion.

Accumulating research data has challenged pharmaceutical company marketing claims about the purported superior efficacy of the more expensive nonclozapine second-generation antipsychotic medications compared to the older and less expensive first-generation antipsychotic drugs (Buchanan et al., 2009). Although this study was underpowered to statistically prove one class of drugs was superior to another, the results are consistent with the published research data, as the first-generation antipsychotic medications performed as well or even slightly better than the secondgeneration antipsychotic medications in rates of restoration of competency (84.4% vs. 73.5%). Because individual patients vary widely in experiencing positive therapeutic response as well as side effects to any single medication trial, these data support the availability of both groups of antipsychotic medicines for flexible use as clinically indicated for competency restoration purposes. Doses of antipsychotic medication treatment for all diagnostic groups in the cohort were generally within the established guideline ranges for treatment of schizophrenia (Buchanan et al., 2009).

In this cohort, the average length of involuntary treatment was slightly more than 4 months, which coincides with the 120-day period of court-ordered treatment allowed in the federal statute under Section 4241(d) of Title 18, United States Code (2012). This is somewhat longer than the treatment response rates described for a group with first episode schizophrenia, who demonstrated treatment response to hallucinations (median = 27 days; M = 59; SD = 104) occurring well ahead of delusions (median = 76 days; M = 150; SD = 239; Gunduz-Bruce et al., 2005). This is also longer than the recommendations that a trial of antipsychotic medication in schizophrenia be at least 2 weeks, with an upper limit of 6 weeks to observe optimal response (Buchanan et al., 2009). One possible explanation is the cohort was primarily composed of chronically ill patients, who might manifest a more delayed response to treatment. Another possibility is more time was needed for medication adjustments in this cohort. A third possibility is mental health clinicians were primarily completing their forensic work product in conjunction with court deadlines. If so, this meant the defendants remained in the facility for the entire 120 days to monitor for longer-term medication efficacy and side effects, as opposed to the clinician completing the forensic report early and transferring the defendant earlier back to a local jail facility. It is also possible that a longer treatment period is required for defendants to experience a remittance in their psychopathology and then have their skills associated with competence to stand trial restored. In other words, the defendants in this study were evaluated from two perspectives: (1) had their mental illness remitted and (2) did they have the capacities associated with competence to stand trial? Regardless, it appears the majority of defendants required only one 120-day period of involuntary medication treatment for restoration of competency status.

Strengths and Limitations

The usual limitations of a retrospective document review apply to this data set. Standard interventions to reduce bias, such as random assignment to assigned treatment groups and the use of a placebo control group, were not possible in this study. As a result, the opinions of the examiners may have been biased in favor of finding a positive response to treatment. However, this was likely offset, to a degree, by the fact that independent judicial review (with opposing expert testimony in many cases) confirmed these findings. Other potential sources of bias in the data set included the lack of standardized clinical assessments using rating scales and diagnostic instruments, the lack of interrater reliability studies, and the lack of blinded outcome measures. As a result, it is possible some patients may have been misdiagnosed or had treatment responses recorded inconsistently across different examiners.

Random assortment and use of a placebo control group will likely never be used in a pretrial population undergoing involuntary treatment for restoration of competency because of ethical and legal issues. If randomly allocating patients is neither practical nor ethical, the principles of evidence-based medicine require clinicians to search for the highest quality available evidence to guide treatment recommendations, such as the observational study design used in the current data set. If treatment effects are "sufficiently large and consistent," carefully conducted observational studies may provide more compelling evidence than poorly conducted randomized controlled studies (Guyatt et al., 2008).

Other factors may have confounded the study results in favor of underestimating the positive response to involuntary medication treatment. No standardized medication protocols were consistently used among the psychiatrists, such as defining the minimum length of time or optimal dosage for an adequate medication trial prior to opining a defendant was not restorable to competency status. Another inconsistency was whether the defendant had to fail one, two, or more medication trials before being viewed as nonrestorable. Serum drug levels were seldom obtained during involuntary treatment, which could have been used to assess for unusually rapid metabolism or noncompliance through "cheeking" oral medication after ingestion at pill line. As a result, some patients may have had a poor clinical response because of an inadequate course of medication treatment.

Other factors beyond medication treatment may also have contributed to the success of restoration and confounded the primary effects of this study. For instance, it is theoretically possible that the Competency Restoration Class (a weekly class whereby defendants are taught courtroom proceedings) or any individual instruction about the legal system that they may have received while hospitalized could have mediated the results. Also, the structure and "supportive" nature of the hospital setting may in some ways have assisted in defendants' recovery. Although it seems very unlikely these ancillary variables would have played any substantive role in restoration for this large group of psychotic individuals, it was not possible to control for these potential effects.

Strengths of the study include the entire cohort being selected in a real-world manner by judicial review of pretrial detainees during a Sell hearing. The cohort included every pretrial felony detainee in the entire United States federal court system treated under the Sell criteria during a complete 6-year period. The diagnostic evaluation process was comprehensive, which included medical assessments and review of available collateral documents from clinical as well as law enforcement sources. The individuals were observed and treated over an extended period of time, typically several months. High rates of agreement in interrater reliability in the diagnosis of schizophrenia-spectrum disorders have been described in the initial field trials of DSM-III and ICD-10 (Sartorius, Ustun, Korten, Cooper, & van Drimmenlen, 1995; Spitzer, Forman, & Nee, 1979), suggesting a high level of confidence in the diagnosis of this cohort. Similar high rates of agreement were found in a recent comparison between defense and prosecution

mental health experts, whether by a psychiatrist or a psychologist, with opposing experts making similar diagnoses of psychotic disorders in defendants charged with serious crimes (kappa scores ranging from .630 to .819; Neilssen, Elliot, & Large, 2010). There is no reason to believe high diagnostic accuracy was not met in the present study as well, especially in light of the extended period of time and comprehensive nature of the evaluation process.

Involuntary treatment proved generally effective in treating defendants in this cohort and restoring their competency, regardless of diagnosis. Because the sample sizes for less commonly diagnosed disorders, such as delusional disorder, were rather small, future research should focus on treatment effectiveness for these rarer disorders. Examining variables that may mediate or moderate the relationship between diagnosis and treatment outcome, is also a next important step in this area of study. Such variables may include comorbid substance abuse, poor educational attainment, or traumatic brain injury. In fact, Mossman (2007) found there were two categories of defendants whose restorability was 35% or lower: defendants diagnosed with irremediable cognitive disorder (e.g., mental retardation) and those diagnosed with long-standing psychotic disorders that resulted in lengthy periods (more than 10 years) of psychiatric hospitalization. Additionally, Colwell and Gianesini (2011) discovered that patients diagnosed with comorbid psychotic and cognitive/intellectual disorders were restored at lower rates. Unfortunately, there were too few comorbidly diagnosed patients in the current study to render these analyses useful. Future projects may further clarify the impact of comorbid disorders on treatment responsiveness and competency restoration.

Finally, although treatment on an involuntary basis to restore competency was effective, a comparison between this population of defendants with those who comply with treatment on a "voluntary" basis may be enlightening. A third group of defendants treated against their will because they become a danger to themselves or others at the facility in which they are housed also exists. Comparisons with this category of defendants may also shed light on the competency restoration treatment process.

Summary

This data set provides empirical evidence of favorable outcomes following involuntary treatment for restoration of competency in a cohort of nondangerous incompetent pretrial defendants. Most medication side effects were easily managed through adjustments in the medication regimen. The majority of defendants were restored to competency within the time frame of a single 120-day court commitment, with similar positive outcomes for first-versus second-generation antipsychotics and for oral medication administration versus intramuscular injection. The favorable outcomes were demonstrated in multiple diagnostic categories following treatment with antipsychotic medication, reflecting the broad therapeutic effects of this class of psychotropic medicine. Although individual cases will vary, the rates of restoration of competency in this cohort surpassed the 70% standard established by federal appellate courts, indicating, in most circumstances, involuntary treatment under the Sell criteria can be considered a "clear and convincing" success.

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