

# Involuntary medication treatment of schizophrenia in the inpatient setting

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#### Abstract

Two Supreme Court cases in the United States describe the use of involuntary medication in individuals with mental illnesses. In addition to these legal requirements, clinicians must also incorporate ethics into treating these individuals, including the principles of autonomy and beneficence. Current guidelines do not provide specific recommendations for choosing an antipsychotic for a patient with schizophrenia who is being treated involuntarily. However, it is recommended that clinicians use general guidelines for the treatment of schizophrenia as a basis for narrowing down appropriate therapy, which may involve the use of long-acting injectable antipsychotics. Clinical considerations that should be accounted for include past medication trials, potential adverse effects, whether tolerability has been demonstrated, route of administration, dosing interval, requirement for oral overlap, comorbid conditions, patient preference, and access to the medication.

Keywords: schizophrenia, involuntary treatment, antipsychotics

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## Introduction

Clinicians may consider involuntary medication treatment of mental illness for patients who are symptomatic but refuse to take medication that will allow them to recover. There are currently 2 Supreme Court cases in the United States describing involuntary medication treatment in nonemergency situations, *Washington v. Harper* in 1990 and *Sell v. United States* in 2003.<sup>1,2</sup> While both cases concern involuntary use of psychiatric medication, there are key differences.

In Washington v. Harper, an incarcerated person diagnosed with bipolar disorder had repeated violent behavior when not taking antipsychotic medication.<sup>1</sup> He was involuntarily medicated in prison, which he subsequently challenged through the legal system. The case made its way to the Supreme Court, where the court ruled an incarcerated individual can be involuntarily medicated if the following 2 criteria are met: 1) the patient is gravely disabled and poses a likelihood of serious harm to themselves or others, and 2) the medication prescribed is in the patient's best interest. This process does not require court intervention as the court leaves the decision to medical professionals; however, the state or facility where the individual is incarcerated may have an internal administrative process that must be followed. Depending on state statute, a short-term court-ordered detention, such as a mandated 96-hour civil involuntary detention in a psychiatric facility, would also qualify the individual for involuntary medication treatment under Washington. The length of the involuntary medication order varies depending on state or facility policy. While data are available on the specifics of state policies, data are lacking on the number of individuals involuntarily medicated annually under Washington.<sup>3</sup>

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### **Take Home Points:**

- 1. The use of involuntary medication in schizophrenia is dictated by federal law and state/facility policy.
- 2. Ethical principles of autonomy, beneficence, and shared-decision making should be considered when developing a treatment plan for involuntary treatment of schizophrenia.
- 3. Clinical considerations for choosing an antipsychotic for involuntary treatment include efficacy, adverse effects, past trials, route of administration, dosing interval, requirement for oral overlap, comorbid conditions, and cost/accessibility.

In contrast, Sell v. United States involves individuals charged with a crime and deemed incompetent to stand trial as a result of mental illness.<sup>2</sup> An earlier court case, Dusky v. United States in 1960,<sup>4</sup> dictates that a defendant must be competent to stand trial, which includes the ability to rationally consult with their attorney and understand the facts of legal proceedings. Individuals not meeting these criteria are deemed incompetent to stand trial. One factor predicting incompetency to stand trial is a diagnosis of a psychotic disorder, such as schizophrenia.<sup>5</sup> In Sell, an individual with no prior history of criminal charges was charged with 56 counts of mail fraud, 6 counts of Medicaid fraud, and 1 count of money laundering. While in the community on bail, his mental illness deteriorated, bail was revoked, and he was additionally charged with conspiring to commit murder. While incarcerated after the bail revocation, he was found incompetent to stand trial. After a series of hearings, the court ruled he could be involuntarily medicated for the purpose of restoring competency to stand trial, thus allowing him to be tried for the charges brought against him. To meet criteria for involuntary medication treatment solely for the purpose of competency restoration, and without regard to the current status of an individual's mental illness, a judge must grant the order, and the following 4 criteria must be met: 1) the individual is charged with a serious crime, 2) there is substantial probability medication will allow the individual to become competent without substantial side effects, 3) no alternative, less invasive treatment is available that would give the same results, and 4) the medication is medically appropriate. There is no standard definition of a "serious" crime, so this is decided on a case-by-case basis by the court; however, a nonviolent, property crime would not likely be considered a serious crime, while a violent crime against a person would be. Of individuals who are found incompetent to stand trial, the most common diagnoses are psychotic disorders, such as schizophrenia.<sup>6</sup> In 2019 alone, there were an estimated 94 000 competency-to-stand trial evaluations in the United States, and the numbers continue to rise.<sup>7,8</sup> As with Washington, data on the number of patients involuntarily medicated annually under Sell is lacking. Not all patients deemed incompetent to stand trial meet the criteria for involuntary medication under these criteria; however, a review of all federal cases from 2003 to 2009 found involuntary medication orders were requested 287 times and granted 46% of the time.<sup>9</sup>

Individuals with guardians may also be involuntarily medicated at the request of the guardian. Laws regarding guardianship vary widely from state to state; however, some states allow guardians to make healthcare decisions, including requiring medication, for individuals under their care.<sup>10</sup> While a full discussion of these regulations is outside the scope of this article, in some states, individuals are not allowed to refuse admission to a psychiatric facility or medication if their guardian deems such treatment necessary.

## **Ethical Considerations**

There are ethical arguments both for and against involuntary treatment in psychiatry, with the main ethical principles involved being autonomy (allowing patients to decide their treatment) and beneficence (doing good).<sup>11–13</sup> To respect these principles in involuntary medication situations, clinicians should ensure they are providing education on the chosen antipsychotic, engaged in shared-decision making when the patient is willing and able to provide input on antipsychotic selection and have the end goal of improving the patient's condition.<sup>12</sup> There is an increasing focus on autonomy in healthcare, and involuntary treatment may seem to be in direct opposition to this ethical principle.<sup>11,12</sup> However, if the goal of involuntary treatment is the recovery of autonomy, involuntary treatment may actually support this ethical principle.<sup>11</sup> Beneficence can be met by creating a plan with the long-term goal of improving the patient's health and safety.<sup>12</sup>

To ensure the principles of autonomy and beneficence are being balanced when considering involuntary treatment, it is recommended to use a transparent review process.<sup>11</sup> This review process should include assessing patient concerns regarding the plan and allowing them to participate in the decision-making when possible. As with any treatment, clinicians should choose a medication where the benefit outweighs the risk, including the decrease in autonomy.

Current American Psychiatric Association guidelines for the treatment of schizophrenia discuss the importance of balancing patient autonomy and self-determination with the patient's best interest.<sup>14</sup> Clinicians should only prescribe involuntary treatment for patients under their direct care after a determination that the patient cannot judge what is in their own best interest, and without treatment, they may cause impairment to themselves or others.<sup>15</sup> This is consistent with the criteria for involuntary medication in the Supreme Court decisions discussed above. In addition, commentary in the *American Medical Association Journal of Medical Ethics* encourages clinicians to maximize compassion, decrease

Ethical	Clinical	Access
Long-term goals	Past trials	Hospital formulary
Patient input in choice of antipsychotic	Use of short-acting antipsychotics	Cost (including cost to patient as outpatient)
Criteria for involuntary treatment	Comorbid conditions	Drug replacement or sample program availability
	Adverse effects	Jail formulary, ability to administer LAIAs, and
	Route	ability to adjust medication times
	Dosing interval	
	Requirement for oral overlap	

LAIAs = long-acting injectable antipsychotics.

<sup>a</sup>Based on expert opinion.

short-term morbidity/mortality, and consider the potential trauma and/or loss of therapeutic alliance when using involuntary treatment.<sup>13</sup> Maximizing compassion involves aligning involuntary treatment decisions with a patient's values and culture, demonstrating sensitivity, and taking measures to ensure existing trauma is not worsened.

## **Risks and Benefits of Medication Options**

A retrospective review of all patients deemed incompetent to stand trial in the United States Federal Court system and involuntarily medicated under Sell criteria from 2003 to 2009 found that 76.5% of patients with schizophrenia were restored to competency with the use of involuntary antipsychotics.9 This restoration rate is consistent with prior studies of incompetent-to-stand-trial patients who were involuntarily medicated.<sup>5,16,17</sup> Haloperidol (41%) and risperidone (27%) were the most commonly used antipsychotics, with 54.5% of patients receiving only intramuscular (IM) medication and 45.5% receiving only oral medication.9 This study also found that one-third of the overall cohort (n = 121) was prescribed beta-blockers or anticholinergic medication to treat side effects. One case of new-onset tardive dyskinesia was reported and attributed to haloperidol decanoate. New-onset diabetes was reported in 2 patients, elevated lipids in 1 patient, and significant weight gain in 2 patients. Based on the restoration rate, which can be seen as a rate of efficacy and low incidence of side effects, the benefit of treatment with antipsychotics likely outweighs the risk in incompetent to stand trial patients with schizophrenia.

Regarding medication choice, there are no specific recommendations from the American Psychiatric Association for involuntary treatment; therefore, clinicians should follow the general recommendations for the treatment of patients with schizophrenia in addition to the considerations in Table 1.<sup>14</sup> Preference is not given to any particular antipsychotic. It is recommended for treatment-resistant patients or patients with a substantial risk of suicide to be treated with clozapine; however, clozapine is especially difficult to give involuntarily as it requires frequent laboratory monitoring that patients may refuse. Available antipsychotic dosage forms include oral tablets/ capsules, orally disintegrating tablets, oral solutions/liquids, short-acting injectables, long-acting injectables, inhalation, and patches. Long-acting injectable antipsychotics (LAIAs) are suggested for use in patients who prefer these agents or in those who have a history of nonadherence (Table 2).<sup>14</sup> LAIAs are an attractive choice for involuntary antipsychotic treatment as they are administered every 2 to 8 weeks, with the option to extend dosing of some to every 3 to 6 months, instead of daily as with oral medications. For individuals who require manual hold or restraint to administer medication, LAIAs have the potential to decrease these specific occurrences of restraint as they are administered less frequently than oral medication. However, before starting an LAIA, there must be a tolerance test of the medication, which can be orally or with a short-acting injectable, depending on the LAIA. Oral medication can be ordered with an IM backup of a short-acting injectable antipsychotic if the oral medication is refused; however, if IM backup is also refused, this will require a manual hold or restraint to administer each refused IM dose. Restraint is associated with physical and psychological injuries to both staff and patients and should be minimized when possible.33,34 In addition, a higher number of IM antipsychotic doses is associated with an increased risk of neuroleptic malignant syndrome.<sup>35,36</sup> Dissolving an oral medication in a beverage or applesauce would require informing the patient that the medication is being administered in this way to not stray into covert medication administration, which is outside regulations for involuntary medication.<sup>12</sup> Based on expert opinion, if oral medication is used, an antipsychotic with once-daily dosing should be chosen to minimize the dosing frequency as much as possible. It may also be difficult to use an antipsychotic that must be given with food in an involuntary patient. Using a patch formulation involuntarily has similar difficulties as oral medications because the patient must be willing to leave the patch on for the specified amount of time. While a short-acting injectable antipsychotic could also be ordered as a backup for refusal of a patch, there are added difficulties because the patient would need to be closely monitored to ensure the patch is not removed.

If a patient has refused initial laboratory monitoring, there is added difficulty and risk in choosing an initial antipsychotic. Obtaining a thorough history is helpful in these

#### TABLE 2: Long-acting injectable antipsychotics<sup>18–32</sup>

Medication	Route	Dosing Interval	Oral Overlap	Short-Acting Injectable Available
Aripiprazole				No
• Aripiprazole monohydrate (Abilify Maintena, Abilify Asimtufii)	IM	Every 1-2 mo	Yes	
Aripiprazole lauroxil (Aristada, Aristada Initio)	IM	Every 1 mo, 6 wk, or 2 mo	Yes <sup>a</sup>	
Fluphenazine decanoate	IM/SQ	2-4 wk	Yes	Yes
Haloperidol decanoate	IM	4 wk	Yes	Yes
Olanzapine pamoate (Zyprexa Relprevv)	IM	4 wk	No	Yes <sup>b</sup>
Paliperidone palmitate				No
• 1-mo formulation (Invega Sustenna)	IM	Every month	No	
• 3-mo formulation (Invega Trinza)	IM	Every 3 mo	No <sup>c</sup>	
• 6-mo formulation (Invega Hafyera)	IM	Every 6 mo	No <sup>c</sup>	
Risperidone		·		No
Risperidone microspheres (Risperdal Consta, Rykindo)	IM	Every 2 wk	Yes	
Risperidone subcutaneous (Perseris)	SQ	Every mo	No	
• Risperidone aqueous suspension (Uzedy)	SQ	Every 1-2 mo	No	
• Risperidone extended-release injectable suspension (Risvan)	IM	Every month	No	

IM = intramuscular; SQ = subcutaneous.

<sup>a</sup>Only 1 dose of oral overlap required if Aristada Initio used.

<sup>b</sup>Risk Evaluation and Mitigation Strategies program does not accept short-acting injectable as tolerance test.

<sup>c</sup>Must receive 4 mo of paliperidone palmitate before starting.

situations, including previous lab results from other facilities if available. Based on expert opinion, the patient should also be informed of the involuntary medication decision and the importance of laboratory and vitals monitoring for safety. As part of this shared decision-making discussion, the patient should be asked about any past adverse effects, allergies, and medical history. These data can guide the clinician in the choice of initial antipsychotic.

Patients being treated involuntarily may refuse to participate in efficacy monitoring. In these cases, completion of the shortened, 6-item Positive and Negative Syndrome Scale can be done based on any conversation the patient is willing to participate in and/or observation as it only includes the following 6 items: delusions, conceptual disorganization, hallucinations, blunted affect, social withdrawal, and lack of spontaneity/flow of conversation.<sup>37</sup> Involuntarily treated patients may also refuse to participate in monitoring of adverse effects. Based on expert opinion, these patients should be approached regularly to reattempt monitoring, such as lab work (hemoglobin A1c, lipid panel, complete blood count, and comprehensive metabolic panel) and vitals (blood pressure, temperature, and weight), as their symptoms resolve. Some monitoring, such as the Abnormal Involuntary Movement Scale for tardive dyskinesia and Barnes Akathisia Rating Scale, can be completed by observation until the patient's symptoms have resolved enough that they are willing to participate in the full exam; however, the Modified Simpson-Angus Scale for drug-induced parkinsonism requires participation of the patient and cannot be done by observation alone. Eliciting reports from the interdisciplinary team is also helpful as other healthcare professionals may recognize adverse effects, such as stiffness, akathisia, or weight gain, through their daily interactions with the patient. If a patient requests as needed (PRN) medication for medical indications, such as pain or constipation, they can also be asked to complete vitals monitoring at that time to monitor for neuroleptic malignant syndrome or metabolic adverse effects.

## Case 1: Treatment Considerations for Involuntary Medication

DN is a 34-year-old patient with a history of schizophrenia admitted to an inpatient forensic psychiatry unit as incompetent to stand trial for charges of attempted murder. DN was prescribed oral risperidone in jail before the current admission and was adherent for 2 weeks with initial improvement in agitation and mood, but has been refusing for the last month. DN was previously admitted to the same hospital 4 years prior as incompetent to stand trial on charges of domestic assault and was restored to competency with quetiapine extended-release 600 mg daily. Medical records from the previous admission show the administration of short-acting fluphenazine and chlorpromazine IM during psychiatric emergencies. DN's body mass index increased from 23 to 27 kg/m<sup>2</sup> while on quetiapine, but no other side effects were reported. During intake for the current admission, DN becomes aggressive and is emergently administered olanzapine short-acting IM, with resolution of agitation and no side effects reported. On exam, DN is noted to be responding to internal stimuli, expresses delusions about being in the Federal Bureau of Investigation and having legal immunity, and denies being previously diagnosed with schizophrenia. All labs are within normal limits, and creatinine clearance is above 120 mL/min. Oral risperidone 2 mg daily is continued from jail; however, DN continues to refuse it. Two months after admission and the continued refusal of all medication, the prosecutor requests a *Sell* hearing, and the involuntary medication order is granted by the judge. The treatment team meets to discuss antipsychotic options. After deciding on a narrowed list of antipsychotics appropriate for DN using the criteria in Table 1 and the long-term goal of remission of schizophrenia, DN is included in the discussion and shared decision-making is used to allow DN to provide input on the antipsychotic selection.

DN has been admitted as incompetent to stand trial, and his crime is considered serious; therefore, the criteria for involuntary medication under *Sell* is applicable. However, DN would not meet the criteria for involuntary medication under *Washington* as he is not gravely disabled and there is not a likelihood of harm to DN or others. The team has also integrated ethical principles into the involuntary medication discussion by setting a long-term goal of remission and incorporating shared decision-making.

The psychiatric pharmacist on the team recommends presenting once-monthly LAIA formulations of risperidone, paliperidone palmitate, or oral quetiapine or risperidone with a short-acting antipsychotic IM backup for refusals as options to DN. Based on expert opinion, an LAIA formulation of risperidone or paliperidone are initial recommendations because DN has demonstrated tolerability to risperidone, showed an initial response to oral risperidone, there are once-monthly formulations available (minimizing dose frequency), there are options that do not require oral overlap, they are appropriate for treatment of schizophrenia and the long-term goal of remission, and paliperidone is the metabolite of risperidone. Paliperidone palmitate has the added benefit of minimal metabolism through the cytochrome P450 system, decreasing potential drug interactions and genetic changes to metabolism. One difficulty using risperidone LAIA or paliperidone palmitate is that DN has not been fully stabilized on oral risperidone, and therefore, a conversion from a stable, efficacious oral dose to an equivalent LAIA is not possible. Instead, the psychiatrist and psychiatric pharmacist should estimate a dose needed based on past trials of other antipsychotics and use this to choose the initial dose, being careful not to overdose. The dose should then be adjusted based on symptom response and/or the emergence of adverse effects. DN has also demonstrated tolerability to fluphenazine; however, oral overlap is required if a loading strategy is not used. DN has not taken fluphenazine long enough to demonstrate improvement, and many clinicians would avoid first-generation antipsychotics if possible due to long-term movement disorder adverse effects. While DN has received and tolerated a dose of short-acting olanzapine IM, the enrollment form for the olanzapine pamoate Risk Evaluation and Mitigation Strategies (REMS) program requires an attestation affirming the patient has tolerated oral olanzapine

and the patient's signature that they have been educated and agree to the medication.<sup>38</sup> No provisions are made for tolerability based on the short-acting injectable. DN has not had an oral dose of olanzapine and must attest to agreeing to the medication. Therefore, DN would not qualify for olanzapine pamoate. In addition, the REMS for olanzapine pamoate requires a 3-hour monitoring period, which may not be possible at the jail or prison DN may be discharged to and, therefore, may not be able to be continued at discharge. DN has not had a history of aripiprazole or haloperidol use, so LAIAs of these antipsychotics are not currently available as options. DN has shown a good response to quetiapine during a past admission. Though using an oral agent may require restraint or manual holds to administer the IM backup for refusal, this option should also be presented to DN as it is the only antipsychotic DN has taken long enough to have a full trial with remission, and DN may prefer to restart this medication. Once an involuntary order is received, patients may choose to voluntarily take oral medication over receiving an LAIA, and the use of the short-acting IM backup may not be necessary.

During the discussion, DN continues to report not needing medication, unwillingness to take oral medication, and not having schizophrenia. The psychiatrist decides to start paliperidone palmitate, and the psychiatric pharmacist recommends a loading dose of 234 mg on day 1, 156 mg on day 8, and 156 mg monthly thereafter. DN was previously restored to competency on a moderately high dose of quetiapine; therefore, targeting a moderate to high dose of paliperidone palmitate (156-234 mg) for the maintenance dose is reasonable. DN should be monitored for efficacy and adverse effects, with adjustments made to the maintenance dose as necessary. Once eligible, DN can be transitioned to the 3- or 6-month formulations of paliperidone LAIA.

## Case 2: Choosing a Medication With No Medication History

LS is a 21-year-old brought to the inpatient psychiatry unit by law enforcement after being found walking in the middle of the street, not dressed appropriately for the weather, and barefoot. Law enforcement reports LS was talking to unseen others and became aggressive when approached. LS was admitted under a civil involuntary detention for a period of 96 hours. On admission, LS exhibited disorganized thought processes, was not oriented to time or place, frequently laughed inappropriately, and was not able to give a reliable history but did report auditory and visual hallucinations. Before admission, LS reports living in the woods. No medication history was available, and LS could not answer questions regarding past medication. LS was diagnosed with schizophrenia and prescribed oral aripiprazole 10 mg daily. LS was not adherent with aripiprazole, and, on day 2 of admission, received 1 dose of haloperidol lactate 5 mg and lorazepam 2 mg IM secondary to an episode of agitation resulting in the assault of another patient. During the

administration of the IM medication, LS was aggressive toward the nursing staff and required physical restraint. LS responded well to the emergency medication, and no adverse effects were reported. Because of nonadherence with oral medication and a history of aggressive episodes, the psychiatrist decided to initiate involuntary medication following facility policy. LS was not willing to participate in a shared decision-making discussion regarding the choice of an antipsychotic. The psychiatric pharmacist recommended using haloperidol decanoate with a loading-dose strategy as the involuntary medication.

Because LS was not charged with a crime and has not been admitted as incompetent to stand trial, the treatment team would be unable to use *Sell* as justification for an involuntary medication order.<sup>2</sup> However, LS does meet the criteria for an order under *Washington v. Harper*, as LS is likely to cause serious harm to others, as evidenced by recent aggressive and assaultive behavior.<sup>1</sup>

Though first-generation antipsychotics are listed as first-line treatment for schizophrenia in guidelines, many clinicians reserve these agents for second-line treatment due to the possibility of movement disorders, such as tardive dyskinesia, and would not use haloperidol decanoate as first-line treatment. However, based on expert opinion, a long-acting injectable would be the best option for LS given the refusal of oral medication, refusal to participate in shared decision-making, and history of aggression when receiving IM medication. As haloperidol is the only known tolerated agent for LS, haloperidol decanoate is the safest to administer. The package insert recommends stabilizing a patient on oral haloperidol and using this dose to convert to an equivalent decanoate dose.<sup>18</sup> Because LS was not stabilized on oral haloperidol beforehand, and the package insert recommends a preferred approach of beginning with lower initial doses and adjusting based on response, the psychiatric pharmacist used a conservative estimate of 10 mg orally per day, with a loading dose of 15x 10 mg (150 mg, split into 2 doses), and a maintenance dose of 10x 10 mg (100 mg). Using a conservative estimate for the oral dose allows the clinician to minimize overmedicating the patient and causing avoidable adverse effects. Oral overlap is recommended for the first 2 to 3 injections if a loading strategy is not used; therefore, it is important to use a loading strategy in patients on involuntary treatment. If a loading strategy is not used, oral overlap with a short-acting IM injection for refusal can be prescribed after a risk-benefit analysis. In situations where the patient will be admitted for a longer duration, such as a patient on a court order, this method may have more risks than benefits; however, for short-term admissions, the benefit may outweigh the risk. As needed (ie, PRN), short-acting IM orders may be placed depending on state and facility protocols for use during episodes of agitation and aggression in the interim. The dose of haloperidol decanoate can be adjusted before the first maintenance dose if the treatment team feels the initial dose was too high (efficacy was seen, but adverse effects emerged) or too low (efficacy was not seen). LS should be asked about medication history again as symptoms of schizophrenia stabilize. If information regarding previous successful trials of a secondgeneration antipsychotic available in an LAIA formulation is gained, clinicians should consider switching to the LAIA formulation of this agent to minimize long-term movement disorders.

## Conclusion

Clinicians are likely to encounter patients needing involuntary treatment of schizophrenia. Federal, state, and facility regulations provide criteria for who may be involuntarily medicated, and clinicians should be familiar with these regulations to provide optimal care. In addition to legal and facility requirements, autonomy and beneficence should also be considered when providing care for these individuals. Ethical concerns can be addressed by involving the patient in shared decision-making regarding the choice of antipsychotic and ensuring long-term goals of treatment are set. While many of the considerations for choosing an antipsychotic are similar to treating voluntary patients, additional consideration should be given to the overall safety of staff and the patient by choosing an antipsychotic with a longer dosing interval, if possible.

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