Involuntary Administration of Long-Acting Injectable Antipsychotics for Competency Restoration

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In implementing the decisions in the landmark case *Sell v. United States*, jurisdictions have adopted mechanisms for the involuntary medication of defendants to restore competency to stand trial. These procedures attempt to balance the liberty and privacy rights of the accused against the government's responsibility to ensure timely prosecution and fair trial. The question of which medications are most appropriate for this goal, however, remains open. This article reviews the legal status of the administration of long-acting injectable (LAI) antipsychotics for sustained competency restoration. We explore case law and discuss the theoretical and empirical benefits and drawbacks to this practice, considering recent technological advancements in LAI development. Some courts have regarded LAI use pursuant to *Sell* as equivalent or superior to immediate-acting medications, whereas others have regarded LAIs as either more intrusive or medically riskier. We conclude that the use of LAIs may be carefully integrated into treatment plans to restore and maintain trial competency amid competing interests.

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It has long been established that patients have a right to refuse medications, even when the decision to do so appears to be contrary to self-interest.[1–3] The right to refuse, however, can be overridden under certain conditions; the rights of prisoners or pretrial detainees, for example, may be limited by competing state interests.[4,5] The question of whether the restoration of trial competency in a mentally ill but nondangerous pretrial detainee may represent another of these situations was answered in the affirmative in the U.S. Supreme Court's 2003 decision, *Sell v. United States*.[6] Since then, individual jurisdictions have developed procedures for *Sell* hearings to consider treatment plans for medications over objection. Unlike emergency situations, which often necessitate the use of short-acting injections of sedative or antipsychotic medications, restoration of trial competency may take place over months and may benefit from long-acting injectable (LAI) antipsychotic drugs. In this article, we explore LAI antipsychotic use pursuant to *Sell* and discuss ways in which the unique properties of LAIs may be of relevance in *Sell* hearings.

Right to Refuse and Forced Medication

The discussion of whether LAIs should be used to restore trial competency in non-consenting defendants should be considered against the backdrop of the evolution of the right to refuse within medical jurisprudence. A person's right to refuse medical interventions is protected on both legal and ethically normative grounds, subsumed under autonomy, a key medical ethics pillar.[7] Beauchamp and Childress point out that "those who lack substantial cognitive and autonomy capacities will not have various decision-making rights such as the right to give informed consent. . . but they will still have rights to life and to

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health care" (Ref. 7, p 84). In general, psychiatric patients have the right to refuse psychotropic medications while hospitalized,[8,9] to take part in treatment decisions,[10,11] and to have judicial review of their competency before receiving forced medications.[12] Ciccone and colleagues,[13] commenting on New York's *Rivers* decision,[12] note that the right to refuse treatment derives broadly from Constitutional Amendments One (free speech [thought]), Eight (cruel and unusual punishment), and Fourteen (due process and equal protection) and generally from privacy rights in Amendments One, Four, Five, and Nine. These right-to-refuse cases pertain to clinical care rather than the rights of prisoners or pretrial detainees in need of competency restoration.

Rights of Prisoners and Pretrial Detainees

In criminal proceedings, constitutional protection of defendants' right to refuse medications remains generally intact, even when it competes with governmental interests. For example, *Winston v. Lee*[14] supported Fourth Amendment protection from unreasonable governmental intrusions. The First Amendment right to freedom of thought and speech should not be abridged by forced psychotropic medications.[15,16] This jurisprudence dates to a post-Civil War case, *People v. Harrington*,[17] in which a California court interpreted the Sixth Amendment's guarantee of fair trial to include freedom from such restraints that may "confuse and embarrass [a prisoner's] mental faculties" (Ref. 17, p 168). A century later, a Washington State decision[16] analogized sedating medications to the physical restraint in *Harrington*, as they too intrude upon a defendant's fundamental right to be (mentally) present at trial, to confront witnesses, and to assist counsel.

Procedural and substantive standards for the proper involuntary medication of criminal detainees have emerged to balance autonomy rights with competing governmental interests, such as *parens patriae* or police power. In *Washington v. Harper*,[4] the Supreme Court held that the interest of a prisoner who is mentally ill and dangerous in avoiding forced medication may be outweighed by the state's interest in reducing the prisoner's dangerousness to self or others. Subsequently, *Riggins v. Nevada*[5] established that involuntary treatment of a pretrial defendant might also be justified if adjudication of guilt or innocence cannot be achieved by less intrusive means. The *Riggins* court, however, did not articulate a specific standard for justifying involuntary administration of medications to achieve timely prosecution.

In 1997, St. Louis dentist Charles Sell was charged with mail fraud, Medicaid fraud, and money-laundering. Amid his pretrial proceedings, he was also charged with the attempted murder of an FBI agent. In 1999, Dr. Sell, who was severely psychotic, was found incompetent to stand trial. He refused medication for competency restoration at a federal hospital. In 2000, a magistrate judge authorized the Medical Center to involuntarily medicate Dr. Sell; Dr. Sell appealed, but the order was upheld by the District Court[18] and the Court of Appeals.[19] The Supreme Court agreed to hear the case.

Drawing upon *Harper* and *Riggins,* the Court ruled that involuntary medications, for the sole purpose of rendering a mentally ill defendant competent for trial, may be allowed if four conditions are met, as summarized in Table 1 below. The *Sell* Court ruled that Missouri had not met its burden, reversing the involuntary-medication order, since the psychiatric findings related to dangerousness, not trial competence. The burden of proof was later judged to be on the government by clear and convincing evidence.[20]

Sell cases typically identify schizophrenia, delusional disorder, or psychotic disorder as the incapacitating conditions requiring antipsychotic medication.[21] The next sections will turn to the question of how antipsychotic medications may be best administered in these circumstances.

Development and Use of LAIs

Treatment with antipsychotic medications has long been dogged by tolerability concerns and variable medication adherence, contributing to subsequent treatment failure.[22] Recognition of the morbidity resulting from patients' discontinuing antipsychotic medications led to the development of LAI formulations.[23,24] Fluphenazine enanthate was developed in 1966, followed by fluphenazine decanoate about 18 months later; formulations of other first-generation antipsychotics (FGAs) were introduced in the 1960's and 1970's.[25] More recently, second-generation (atypical) antipsychotics (SGAs), such as aripiprazole, olanzapine, risperidone, and paliperidone, have also become available as LAI formulations (see Table 2).

Table 1 Legal Elements for Involuntary Medication to Restore Trial Competency (from *Sell v. U.S.*[6])

Element	Criteria
1	Important government interests are at stake
2	Medication is substantially likely to render the defendant competent to stand trial and substantially unlikely to have side effects interfering with the fairness of the trial
3	Medication is necessary to further government interests and less intrusive treatments are unlikely to achieve the same results
4	Medications are "medically appropriate"

Efficacy and Adverse Effect Comparisons

The psychiatric literature has suggested superior efficacy of LAIs over their oral counterparts, based on more reliable drug delivery mechanisms, reduced differences in peak and trough plasma levels, and improved patient adherence to a medication schedule.[26–28] A meta-analysis by Park and colleagues[23] found that, compared with oral SGAs, LAI SGAs had greater efficacy in terms of relapse prevention, medication adherence, and, in studies longer than a year, greater efficacy in remission rates. Accordingly, LAIs have been shown in mirror-image studies to lead to decreased hospitalization rates in patients with psychotic disorders.[29,30] Since their introduction into clinical practice in the 1960s, LAIs have been used mainly for maintenance in patients with psychotic disorders, although data from placebo-controlled, randomized clinical trials indicate that they also reduce symptoms when administered as first-line therapy in acutely ill patients.[31–33]

Because LAIs avoid first-pass metabolism in the liver and achieve bioavailability at lower dosages, they have been theorized to have a more favorable side-effect profile compared with other preparations.[26] Analysis of existing data, however, indicates that side effects associated with LAIs generally follow the known side-effect profiles of the corresponding oral medication.[30] A meta-analysis of head-to-head comparisons of LAIs to their oral counterparts showed no increase in adverse side effects in LAIs in over 90 percent of recorded outcomes, and no increase in treatment discontinuation or death in those taking LAIs.[34] The few side effect differences noted were akinesia (higher with LAIs), low-density lipoprotein cholesterol change (higher with LAIs), anxiety (higher with LAIs), and prolactin change (lower with LAIs).[34] The evidence on whether LAIs induce more extrapyramidal side effects (EPS) compared with their oral counterparts is mixed. A meta-analysis of 18 randomized controlled trials suggests that LAIs induce less EPS compared with their oral counterparts.[35,36] In contrast to these findings, other meta-analyses suggest that LAI SGAs carry greater risk of EPS.[23,37] Misawa and colleagues,[34] however, note that it is unclear what percentage of this increased risk can be attributable to concomitant oral antipsychotic dosing during LAI initiation. Because of this lack of definitive data on overall side effect risk, coupled with other concerns including potentially longer time to reach steady state as well as longer side effect duration, LAIs are rarely used as a first-line approach in acute illness and are typically initiated after a patient demonstrates tolerability to a trial of oral medication.[34]

Forensic Applications

Despite their clinical efficacy, LAIs have received scant attention in the forensic psychiatric literature, perhaps reflecting the tendency of medical advancements to outpace changes in jurisprudence and legislation. Herbel and Stelmach[38] described the successful use of haloperidol decanoate monotherapy and fluphenazine decanoate monotherapy in restoring individuals with delusional disorders to competency. Freeman and Frierson[39] described guidelines for court-mandated involuntary administration of LAI antipsychotics as a condition of supervised release. A study of defendants in Connecticut receiving antipsychotic medications over objection indicated that some received LAIs.[40] Although the literature indicates that LAIs are being administered to non-dangerous defendants to achieve or maintain competency, to date no study has systematically reviewed or characterized this application.

The sections that follow review the legal status of using involuntary LAI antipsychotics for the purpose of competency restoration, and comment on the theoretical and empirical benefits and drawbacks of using LAI antipsychotics for this purpose. For the purposes of this article, the definition of "involuntary administration of medications" includes instances in which the patient physically resists medications but excludes those in which the patient takes medications only under a court order.

Post-*Sell* Case Law

To review how states have implemented the *Sell* criteria in considering involuntary administration of

Table 2 Long-Acting Injectable Antipsychotic (LAI) Medication Comparisons

Long-Acting Injectable Antipsychotic	Antipsychotic Class	Delivery	Prerequisite to Delivery	Dosing Interval Method	Requires Oral Supplement after Initial Injection	Requires Loading Dose	Notable Side Effects	Notable Properties
Fluphenazine decanoate	1st generation	IM or SQ	Establish tolerability with any shorter-acting form of fluphenazine	Up to 6 weeks (individualized for each patient)	No	No	Weight gain, metabolic syndrome, EPS,[c] tardive dyskinesia, QT prolongation	Low monetary cost; highest risk of EPS, tardive dyskinesia (irreversible; risk increases with increased treatment duration and dose; much less common in short treatment periods)
Haloperidol decanoate	1st generation	IM	Establish tolerability with any shorter-acting form of haloperidol	4 weeks	No	No	Weight gain, metabolic syndrome, EPS,[c] tardive dyskinesia, QT prolongation	Low monetary cost; highest risk of EPS, tardive dyskinesia (irreversible; risk increases with increased treatment duration and dose; much less common in short treatment periods)
Olanzapine pamoate (Zyprexa Relprevv)	2nd generation	IM	Establish tolerability with oral olanzapine	2 or 4 weeks	No	No	Post-injection syndrome,[d] weight gain, metabolic syndrome	Risk of post-injection syndrome
Risperidone microspheres (Risperdal Consta)	2nd generation	IM	Establish tolerability with oral risperidone	2 weeks	Yes, 3 weeks	No	Hyperprolactinemia, galactorrhea, weight gain, sometimes EPS	Shortest-acting injectable antipsychotic on this list
Paliperidoneb palmitate (Invega Sustenna)	2nd generation	IM	Establish tolerability with oral risperidone, oral paliperidone, or injectable risperidone	4 weeks	No	Yes	Hyperprolactinemia, galactorrhea, weight gain, sometimes EPS	Requires loading dose, but can be administered monthly after second injection
Paliperidoneb palmitate (Invega Trinza)	2nd generation	IM	Establish tolerability with Invega Sustenna paliperidone palmitate (at least 4-month trial)	3 months	No	No	Hyperprolactinemia, galactorrhea, weight gain, sometimes EPS	Requires 4-month trial of tolerability with Invega Sustenna prior to initiation of this longer-acting injectable antipsychotic
Risperidone RBP-7000 (Perseris)	2nd generation	SQ	Establish tolerability with oral risperidone	4 weeks	No	No	Hyperprolactinemia, galactorrhea, weight gain, sometimes EPS	Does not require oral supplementation or loading dose
Aripiprazole monohydrate (Abilify Maintena)	2nd generation	IM	Establish tolerability with oral aripiprazole	4 weeks	Yes, 2 weeks	No	Akathisia	Requires 2 weeks of concomitant administration of oral medication after initial injection

Table 2 Continued

Long-Acting Injectable Antipsychotic	Antipsychotic Class	Delivery	Prerequisite to Delivery	Dosing Interval Method	Requires Oral Supplement after Initial Injection	Requires Loading Dose	Notable Side Effects	Notable Properties
Aripiprazole lauroxil (Aristada)	2nd generation	IM	Establish tolerability with oral aripiprazole	4, 6, or 8 weeks (depending on dose)	Yes, 3 weeks	No	Akathisia	Requires 3 weeks of concomitant administration of oral medication after initial injection

All above information obtained from each medication's respective prescribing information/package insert.
[a]IM = intramuscular; SQ = subcutaneous.
[b]paliperidone is the active metabolite of risperidone.
[c]EPS (extrapyramidal side effects) include: dystonia, akathisia, parkinsonism, tardive akathisia, tardive dyskinesia; risk is higher with FGAs than with SGAs.
[d]Post-injection syndrome refers to the combination of symptoms consistent with olanzapine overdose and may include severe sedation or delirium. Patients who receive olanzapine pamoate must be monitored for 3 hours after injection by a healthcare professional.

LAIs for competency restoration, we conducted a literature search without language restriction using Nexis Uni, Google Scholar, and MEDLINE/PubMed. Search terms included synonyms of competency restoration; involuntary antipsychotic; neuroleptic; depot; long-acting injection; decanoate; palmitate; enanthate; Sell; and competency restoration. Query of state statutes did not return guidelines regarding the specific of LAIs over objection to criminal defendants hospitalized for competency restoration.

Approval of LAI Antipsychotics in Sell *Hearings*

Review of case law disclosed several instances in which courts approved involuntary LAI medications for competency restoration under a *Sell* analysis.

United States v. Evans[41,42]

Herbert Evans, who was diagnosed with paranoid schizophrenia, was charged with, among other things, threatening to murder a magistrate judge. He was found incompetent to stand trial but refused to take antipsychotic medications. At a *Sell* hearing in 2004, the court granted the government's request for involuntary medication. On appeal, however, the appellate court agreed with Mr. Evans that the government did not meet the second and fourth elements of *Sell*. The government resubmitted a new treatment plan, which involved first attempting to persuade Mr. Evans to take oral starting doses of 0.5 mg of risperidone or, if Mr. Evans refused, by nasogastric tube. If tolerated, the medication would be initiated with short-acting risperidone injections, followed by the LAI formulation. The plan included side-effect monitoring with specific attention to Mr. Evans's diabetes and hypertension and alternative medications, such as LAI haloperidol, should Mr. Evans's symptoms fail to respond to risperidone.

The court found that the new proposal satisfied the second and fourth *Sell* elements, and specifically noted that an LAI would "reduce the necessity for forceful encounters with Evans in administering the medication" and that an SGA LAI such as risperidone carried less risk for neuromuscular side effects compared with haloperidol (Ref. 42, p 704). The court ultimately approved the proposed plan with caveats that test doses not be administered via nasogastric tube and that medication administration cease

should Mr. Evans's diabetes worsen to the point of requiring insulin.

United States v. Sherrill[43]

James Sherrill, indicted on charges of drug possession and distribution, was found incompetent to stand trial secondary to delusional disorder and was committed to the Butner facility for competency restoration. The treating psychiatrist opined that the appropriate treatment for Mr. Sherrill's psychosis was antipsychotic medication and that his poor insight and refusal to take medication was an indication for an LAI. Mr. Sherrill would first be offered an oral antipsychotic, followed by the corresponding short-acting injectable should he refuse the oral formulation. Only after he demonstrated tolerability with short-acting medication would he be given an LAI. The district court held that the government established all four *Sell* elements by clear and convincing evidence. Notably, the court considered but rejected alternative treatments, including psychotherapy, to build rapport with Mr. Sherrill and persuade him to take medications voluntarily, citing a psychiatrist's testimony that "we're beyond the rapport-building stage" (Ref. 43, p 1016).

United States v. Grape[44]

The Third Circuit similarly affirmed a district court's order for a defendant to be forcibly medicated with an LAI. John Grape, who had chronic mental illness, had been found incompetent to stand trial on child pornography charges. Remanded to the United States Medical Center in Springfield, MO for competency restoration, he was ordered to receive an LAI pursuant to *Sell.* Mr. Grape challenged the decision, arguing that the government did not satisfy elements one and two of the *Sell* test. The appellate court affirmed the district court's order. Of note, the appellate court, in considering whether the government satisfied the first *Sell* element, took into account the seriousness of Mr. Grape's crimes and the facts of his individual case, remarking that "[t]he fact that Grape has already been involuntarily medicated [pursuant to *Harper*] and has been restored to competency diminishes his countervailing [liberty] interest" (Ref. 44, p 603).

Rejection of LAI Antipsychotics in Sell *Hearings*

Review of case law also disclosed several instances in which courts rejected involuntary LAI medications for competency restoration.

United States v. Onuoha[45]

The Ninth Circuit ruled against the involuntary administration of LAIs to restore trial competency. Nna Alpha Onuoha, who was diagnosed with paranoid schizophrenia, had been charged with, among other things, making threats to the Los Angeles International Airport the day before the anniversary of the 9/11 terrorist attacks. The district court approved The Bureau of Prisons' (BOP) proposed treatment plan to administer short-acting haloperidol and, if tolerated, to give loading doses of LAI haloperidol at 150 mg every two weeks followed by monthly maintenance doses of 150 to 200 mg. Mr. Onuoha appealed, arguing that the treatment plan failed to satisfy the fourth *Sell* element. The appellate court agreed, pointing out that the proposed doses of haloperidol were higher than those recommended in the BOP guidelines and that the treatment plan did not abide by the haloperidol package insert recommendations to administer LAI only after establishing tolerability of the short-acting injection. The court concluded, "We acknowledge that courts must rely on the testimony of medical experts in evaluating the constitutionality of involuntary medication. But a physician's word is not absolute, not even the word of a reputable and experienced doctor" (Ref. 45, p 1059).

United States v. Magnolia[46]

An Arizona federal court rejected a proposed treatment plan with an LAI on grounds that it did not satisfy the fourth *Sell* element. Imani Magnolia, who was diagnosed with delusional disorder, was charged with, among other things, filing false liens, and was found incompetent to stand trial. The government sought to involuntarily medicate her with LAI haloperidol pursuant to *Sell.* The district court rejected the proposal, finding that involuntary LAI treatment was not in her best medical interest because her delusions did not impair her ability to carry out activities of daily functioning, the risk of side effects outweighed the benefits of competency restoration, and her delusions would resume after discontinuation of the LAI after trial. In reaching the decision, the *Magnolia* court cited *Ruiz-Gaxiola,*[20] in which the risks of potential medication side effects were found to outweigh the benefit of potential competency restoration. Specifically, the *Ruiz-Gaxiola* court had reasoned that "the medical benefit of becoming competent to stand trial for only a few months (even

if that outcome were likely) and then returning to [the defendant's] prior state of Delusional Disorder could not outweigh even a miniscule [sic] risk of a disfiguring and potentially irreversible side effect" (Ref. 20, p 706).

Discussion

The properties of LAIs that differentiate them from their shorter-acting oral or injectable counterparts carry implications in *Sell* hearings. Some of these properties may make LAIs superior to other formulations when medicating defendants under a court order.

LAIs and the First Sell *Element*

The first *Sell* element, whether the government has an important interest in bringing the defendant to trial, hinges on the seriousness of the crime and the facts of the individual case, with no medical implications (notwithstanding a possible exception of the *Grape* court's finding that the defendant's countervailing liberty interest was diminished because he had previously received involuntary medications). The case law appears to show that there is a sliding scale within the first *Sell* element, such that the state would need a greater interest to order LAI use versus ordering that the defendant accept oral or short-acting formulations.

The other three *Sell* elements, however, consider the efficacy and side effects of proposed medication, whether the medication is appropriate given the defendant's medical history, and whether there are less intrusive alternatives for treatment. A medication's formulation, route of administration, and length of action affect these considerations.

LAIs and the Second Sell *Element*

The second *Sell* element requires courts to determine whether forced medication would significantly further state interests. Medications must be substantially likely to render the defendant competent to stand trial and substantially unlikely to have side effects reducing the defendant's ability to assist counsel. Antipsychotics generally fulfill this criterion for psychosis, except if oversedating. They predictably improve disordered thinking and usually do not result in side effects that incapacitate a defendant during trial. Although *Sell* offers no bright-line definition of the "substantially likely" threshold, the Second Circuit has accepted evidence of a seventy percent success rate of antipsychotics in restoring competency.[47]

Evidence suggests that LAIs perform similarly to, or better than, their oral counterparts in achieving remission of symptoms.[23] Since choosing a medication to achieve and maintain competency through the end of trial implies a treatment timeline of weeks to months, LAIs may have a considerable advantage over their short-acting counterparts in maintaining competency restoration. A shown in Table 2, the typical duration of action of an LAI is two to four weeks, although recently approved LAI formulations extend the action of the antipsychotic for up to eight weeks (aripiprazole lauroxil, approved July 2018)[48] or three months (paliperidone palmitate, approved May 2015).[49] Some newer LAI formulations can be administered without a loading dose or supplemental oral medication. For example, RBP-7000, a long-acting subcutaneous risperidone injectable approved in July 2018, reaches clinically relevant levels after one injection without a loading dose or oral cross-coverage.[50] Notwithstanding mixed evidence on their risk of inducing EPS, LAIs' side effect profiles appear overall similar to that of their oral counterparts, with less drug discontinuation.[34–36]

Although LAIs carry a risk of akinesia, akathisia, and sedation, whether a defendant will experience these adverse effects is difficult to predict.[51] Whether such side effects would reduce a defendant's ability to assist counsel and therefore render a trial unfair is also not a given. In *United States v. Mesfun*,[52] the court acknowledged the sedating effects of risperidone but determined that such effects would not impair the defendant's ability to assist counsel.

LAIs and the Third Sell *Element*

The third *Sell* criterion requires the courts to consider whether medication is necessary to further government interests, meaning that there are no alternative and less intrusive treatments to restore a defendant to competency. This element is generally seen as satisfied by antipsychotic medication in cases where the defendant is incompetent due to psychosis. When, as in *Sherrill*,[43] the defendant's psychotic illness extends "beyond the rapport-building stage," no alternatives exist.

Both the American Psychological Association[53] and the American Psychiatric Association (along with the American Academy of Psychiatry and the Law)[54] filed

amicus briefs to the Supreme Court deciding *Sell*. The American Psychological Association urged the court to first consider less-intrusive, non-drug treatments in competency restoration but acknowledged that psychotherapy is often not adequate by itself to treat acute psychotic disorders. In its brief, the American Psychiatric Association noted that "[a]ntipsychotic medications are not only an accepted but often essential, irreplaceable treatment for psychotic illnesses" and that data do not support the substitution of medications with psychotherapy (Ref. 54, p 13).

The question remains, within the panoply of antipsychotic medications, as to which ones are less "intrusive." Operationalizing "intrusiveness" would lend further guidance on whether LAIs are more or less legally intrusive compared with other preparations. Acknowledging the *amicus* briefs above, the *Sell* decision instructed lower courts to use "less intrusive means for administering the drugs, e.g., a court order to the defendant backed by the contempt power, before considering more intrusive methods" (Ref. 6, p 181). In so doing, the Court appears to imply that involuntary medications given via injection or through nasogastric tube are more intrusive than those taken by mouth under court order. As Klein[55] noted, the court does not explicitly outline why the "voluntary" taking of medications under threat of contempt would not undermine the defendant's liberty interest in refusing medications.

In the absence of further guidance from the *Sell* court on operationalizing intrusiveness, courts may settle on their own definitions. A 1976 Minnesota Supreme Court[56] decision identified six parameters of intrusiveness:

> The extent and duration of changes in behavior patterns and mental activity effected by the treatment, the risks of adverse side effects, the experimental nature of the treatment, its acceptance by the medical community of this state, the extent of intrusion into the patient's body and the pain connected with the treatment, and the patient's ability to competently determine for himself whether the treatment is desirable (Ref. 56, pp 262–63).

The Alaska Supreme Court[57] acknowledged that the "truly intrusive nature of psychotropic drugs may be best understood by appreciating that they are literally intended to alter the mind. . . [and] many states have equated the intrusiveness of psychotropic medication with the intrusiveness of electroconvulsive therapy and psychosurgery" (Ref. 57, p 242).

Although injected medications may be more painful than oral medications, they are the only route of administering antipsychotics involuntarily to a defendant who physically resists medications (barring the administration of crushed medications via nasogastric tube, a far more dangerous and intrusive undertaking than injected medications).[41] If, as in *Evans*,[41] the court is interested in reducing the number of "forceful encounters" with a defendant, each of which may be traumatic both to the defendant and to medical staff, LAIs may offer a superior solution. LAI antipsychotics that provide faster dissolution of medication and more rapid achievement of therapeutic levels may thus be less intrusive compared with short-acting injectable antipsychotics, which may need weeks of daily injections to achieve clinically therapeutic effects. Pain and discomfort associated with injections may also be minimized through selecting water-based SGA LAIs, which are less painful than the older, oil-based depot antipsychotics, as well as selecting agents with smaller injection volumes or longer injection intervals.[30]

Even though LAIs' duration of action may be a desired property in achieving and maintaining trial competency (second *Sell* element), it can also be a drawback in regard to a medication's intrusiveness (third *Sell* element) as defined by duration of its effects on thoughts or behavior. This is the principal reason that LAIs are not first-line selections for this indication. Perhaps the most important consideration in determining a medication's intrusiveness is the defendant's values and preferences, as the 1981 *Rennie* appellate decision court points out: "[t]he least intrusive means standard does not prohibit all intrusions. It merely directs attention to and requires avoidance of those which are unnecessary or whose cost benefit ratios, weighed from the patient's standpoint, are unacceptable" (Ref. 9, p 847).

LAIs and the Fourth Sell *Element*

The fourth *Sell* criterion requires that the court consider whether the proposed medications are medically appropriate, meaning they are in the best medical interest of the defendant in the context of the individual's medical history. Whereas the second *Sell* element considers medication side effects that may affect the defendant's ability to assist counsel, the fourth broadens the inquiry to include other potentially dangerous or unwanted effects that may not influence the fairness of trial but nevertheless affect a defendant's clinical trajectory. As noted above, the

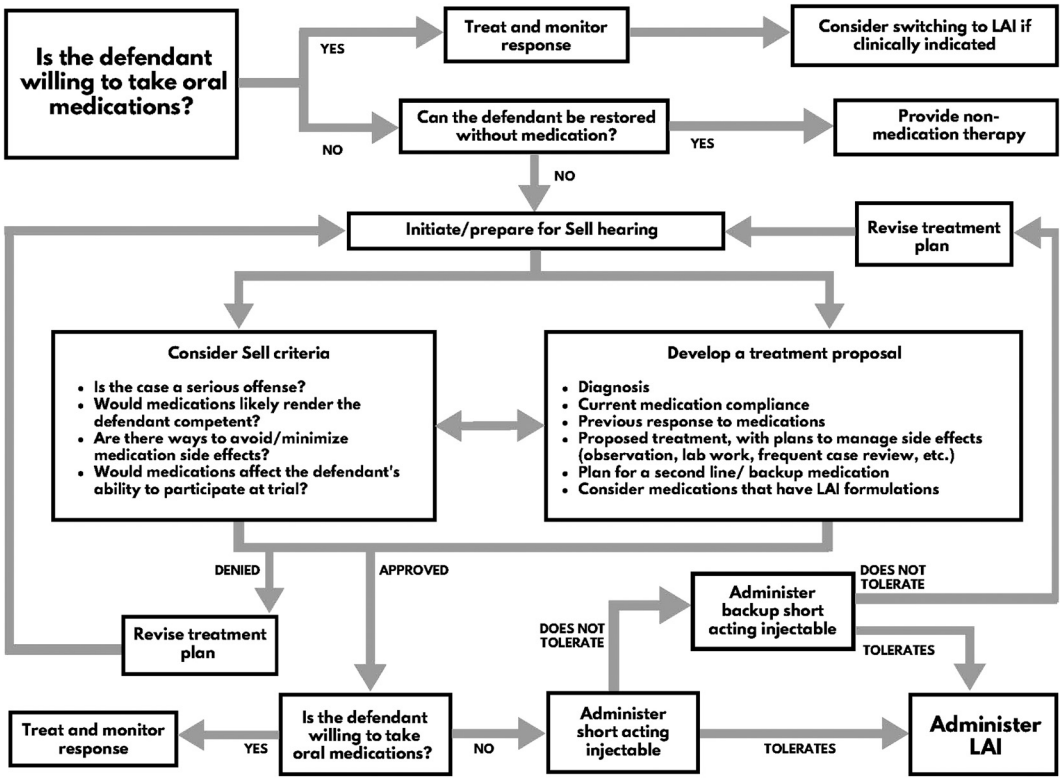

Figure 1. Treatment planning for competency restoration with antipsychotics.

side effect profile of LAIs closely follows that of their oral counterparts, with possibly less akinesia, low-density lipoprotein cholesterol change, anxiety, and prolactin fluctuation. Nevertheless, courts considering the fourth *Sell* element may balk at an LAI as a first choice given its duration of action in relation to adverse events. The defendant's medical history, as well as preferences and concerns about weight gain, metabolic adverse effects, and sexual functioning, need be addressed on an individual basis. The question of LAIs versus other injectables versus oral forms of antipsychotic medication can be considered in light of the following section.

Including LAIs in Treatment Planning

Contemplating treatment over objection for the sole purpose of restoring trial competency, the treating facility would provide a treatment plan to the court that has contingencies at various junctures. With consideration of the interplay between LAIs and the *Sell* criteria, the decision tree shown in Figure 1 illustrates decision-making pathways when considering treatment choices, including when and whether to introduce LAIs in competency restoration. At various intercept points, a defendant may choose oral or LAI medication without a court order. Forced medication, per the current standard of care (fourth *Sell* element), would not include an LAI at the outset.

Restoration of competency via reduction in active psychotic symptoms includes time elements, such as hiatus between jail and hospital and between improvement and trial. This situation differs from emergency forced medication of a dangerous individual in jail. As Ash and colleagues[58] observed, jail-based competency restoration programs have the advantages of timeliness and the possibility of incorporating a *Sell* hearing into the treatment plan in advance of transfer to a hospital setting, where treatment is initiated. Although involuntary medication was not permitted at the jail, early initiation of the *Sell* hearing potentially shortened the hospitalization in the ensuing phase and did not require hospital staff to testify in court. While the authors did not address the matter of route of administration, another potential advantage is that advance permission to include LAI therapy in the treatment plan could have the desired effect of maintaining competency, not simply restoring it in the short term. In practice, many defendants faced with a court order

to treat will agree and not need to face forced administration.

Conclusion

Available psychiatric literature suggests that LAIs are equally if not more efficacious compared with oral antipsychotics and carry a similar side effect profile to oral antipsychotics. Their unique properties, including more rapid achievement of therapeutic levels requiring fewer forceful encounters and longer duration of action, may make them better choices for restoring and maintaining trial competency. It appears that courts hearing *Sell* cases are not averse to varied routes of administration as long as the legal elements are satisfied. Whether or not LAIs are a more intrusive medication compared with oral or short-acting injectables may depend on whether intrusiveness is defined by duration of action or by aggregate pain and discomfort, a case-by-case consideration.

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