IN THE
COURT OF APPEALS OF MARYLAND

No. 47
September Term, 2006

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Appellant,

v.

ANTHONY KELLY,

Appellee.

On Appeal from the Circuit Court for Baltimore City
(Albert J. Matricianni, Jr., Judge)

BRIEF FOR THE AMERICAN CIVIL LIBERTIES UNION OF MARYLAND, THE JUDGE DAVID L. BAZELON CENTER FOR MENTAL HEALTH LAW, THE NATIONAL COUNCIL FOR COMMUNITY BEHAVIORAL HEALTHCARE, AND THE NATIONAL MENTAL HEALTH ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

David Rocah
American Civil Liberties
Union Foundation of Maryland
3600 Clipper Mill Rd.
Suite 350
Baltimore, MD 21211
(410) 889-8555

John Townsend Rich*
Melissa Briggs Hutchens*
Goodwin Procter LLP
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 346-4000

*Not admitted in Md., motions for special admission pending

September 1, 2006

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES: **Page**

STATUTES:

ARTICLES AND TREATISES:

Shirzadi, Arshia A., & S. Nassir Ghaemi, *Side Effects of Atypical Antipsychotics: Extrapyramidal Symptoms and the Metabolic Syndrome*, 14 Harv. Rev. Psychiatry 152 (2006) 16, 18, 19

Siegal, David M., *et al.*, *Old Law Meets New Medicine: Revisiting Involuntary Psychotropic Medication of the Criminal Defendant*, 2001 Wis. L. Rev. 307 (2001) 8

Silva, Sara P., *et al.*, *To Believe or Not to Believe: Cognitive and Psychodynamic Approaches to Delusional Disorder*, 11 Harv. Rev. Psychiatry 20 (2003) 14

Simpson, George M., *Atypical Antipsychotics and the Burden of Disease*, 11 Am. J. Managed Care S235 (Supp. Sept. 2005) 19

Smith, Douglas A., & Peter F. Buckley, *Pharmacotherapy of Delusional Disorders in the Context of Offending and the Potential for Compulsory Treatment*, 24 Behav. Sci. & L. 351 (2006) 12, 21-22, 24

Stanley, Barbara, *et al.*, *Preliminary Findings on Psychiatric Patients as Research Participants: A Population at Risk?*, 138 Am. J. Psychiatry 669 (1981) 8

U.S. Food & Drug Admin., *Patient Information Sheet: Olanzapine (marketed as Zyprexa)* (Apr. 2005), http://www.fda.gov/cder/drug/InfoSheets/patient/olanzapinePIS.htm 18, 20

U.S. Food & Drug Admin., *Patient Information Sheet: Quetiapine Tablets (marketed as Seroquel)* (Apr. 2005), http://www.fda.gov/cder/drug/InfoSheets/patient/quetiapinePIS.htm 18, 20

U.S. Food & Drug Admin., *Patient Information Sheet: Risperidone Tablets (marketed as Risperdal)* (Apr. 2005), http://www.fda.gov/cder/drug/InfoSheets/patient/risperidonePIS.htm 18, 20

U.S. Food & Drug Admin., Public Health Advisory, *Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances* (Apr. 2005), http://www.fda.gov/cder/drug/advisory/antipsychotics.htm 20

Watters, Terri, *Competence to Stand Trial With Forced Medication: Placing Defendants in Harm's Way*, 5 J. Forensic Psychol. Prac. 79 (2005) 10

Wilkaitis, John, *et al.*, *Chapter 27: Classic Antipsychotic Medications*, *in* The American Psychiatric Press Textbook of Psychopharmacology 425 (3rd ed., Alan F. Schatzberg & Charles B. Nemeroff, eds., 2004) 15, 16, 17

Winick, Bruce J., The Right to Refuse Mental Health Treatment (1997) 10

INTEREST OF THE *AMICI*

The American Civil Liberties Union of Maryland is the state affiliate of the American Civil Liberties Union (ACLU), a nationwide, nonprofit, nonpartisan organization with more than 500,000 members. From its founding in 1920, the ACLU has devoted itself to protecting the constitutional rights and individual liberties of all Americans. Since 1963, the ACLU has studied issues relating to the involuntary commitment of psychiatric patients and advocated increased procedural protections for such patients. The ACLU of Maryland, which is comprised of more than 14,000 members, carries out the ACLU's mission in this state through an active program of litigation in defense of civil liberties.

The Judge David L. Bazelon Center for Mental Health Law is a national public interest organization founded in 1972 to advocate for the rights of individuals with mental disabilities. The Center has engaged in litigation, policy advocacy, and public education to preserve the civil rights of and promote equal opportunities for individuals with mental disabilities in institutional as well as community settings. It has litigated numerous cases concerning the rights of people with mental illness or mental retardation, including the right to refuse treatment by antipsychotic drugs.

The National Council for Community Behavioral Healthcare is a not-for-profit association of 1,300 behavioral healthcare organizations that provide treatment and rehabilitation for mental illnesses and addictions disorders to nearly six million adults, children and families in communities across the country. Serving as the national voice of the provider community, the National Council advocates within all levels of government

to ensure all adults, children and their families have access to quality behavioral healthcare.

The National Mental Health Association ("NMHA") is the country's oldest and largest nonprofit mental health organization. NMHA has over 340 affiliates who are dedicated to improving the mental health of all Americans, especially the 54 million people who have severe mental disorders. Through various forms of advocacy, education, research, and service, the NMHA helps to ensure that the mentally ill are accorded respect, dignity, and the opportunity to achieve their full potential. The NMHA is deeply committed to enabling the mentally ill to blossom into fully functional adults who are free from the burdens of stigma and prejudice often imposed upon them by society.

QUESTION PRESENTED

Whether Section 10-708 of the Health-General Article of the Maryland Code permits the State to forcibly medicate involuntarily committed patients with mental illness who have elected to refuse treatment with antipsychotic drugs and who have not been found incompetent to make treatment decisions about themselves, absent a finding that they present a danger to themselves or others within the hospital environment.

STATEMENT OF THE CASE

Amici adopt the Statement of the Case in the Brief of Appellee.

INTRODUCTION AND SUMMARY OF ARGUMENT

The State and *amici* supporting its position make two policy arguments in support of the State's statutory interpretation of Section 10-708 of the Health-General Article of the Maryland Code and its argument that this interpretation is constitutional: (1) the State should be able to forcibly administer antipsychotic drugs because forced medication is the only hope for treatment, and (2) the State is in the best position to make treatment decisions for involuntarily committed individuals.

In this brief, we write to respond to these policy arguments. We leave to the Appellee's Brief the issues of what the General Assembly meant when it passed Section 10-708 to specify the circumstances under which involuntarily committed patients may be treated against their will and whether the State's interpretation of that statute is permissible under the regular canons of statutory construction, including the avoidance of constitutional issues.

The State and its *amici* argue that Appellee's interpretation would be to the detriment of the care and treatment of institutionalized individuals and would subvert the goal of providing treatment so that individuals can be safely returned to the community. According to the State and its *amici,* if the State cannot forcibly medicate competent patients who refuse medication but who are not dangerous within the hospital, like Mr. Kelly, such patients are "condemned to lifelong commitment." State's Brief at 12. According to the State, the idea that the legislature would recognize the rights of

committed but competent individuals to refuse medication "ignores common sense or logic." *Id.*[1]

We show that, contrary to the State's assertions, Appellee's interpretation does not defy common sense or logic and, in fact, is in accord with Maryland law and well-grounded concerns about the efficacy and dangers of antipsychotic drugs. First, Maryland law recognizes that committed individuals may remain able to make treatment decisions and that the forced administration of drugs seriously infringes upon an individual's fundamental rights. Second, antipsychotic drugs are not the panacea to mental illness that the State and its *amici* portray them to be in their briefs. Particularly for delusional disorder, the condition with which Mr. Kelly was diagnosed, there is an absence of convincing evidence documenting the efficacy of the these drugs. Moreover, these drugs have potentially devastating side-effects, the risks of which can outweigh the potential benefits. Finally, forced medication can work at cross-purposes with the State's espoused goal of providing effective treatment.

In short, a competent patient's refusal to take these drugs may be rational and not deluded, and there are therapeutic as well as civil liberties reasons for honoring such a refusal.

---

[1] The State's *amici* take this position even further and argue that it would actually contravene a patient's liberty interests to forbid the State to medicate a patient against his or her will. Brief of the Maryland Psychiatric Society *et al.* as *Amici Curiae* at 17.

ARGUMENT

I. Maryland Law Recognizes That the Forced Administration of Antipsychotic Drugs Seriously Impinges Upon an Individual's Fundamental Rights and Presumes That Committed Individuals Are Competent To Make Treatment Decisions.

A. Maryland Law Recognizes That the Forced Administration of Drugs Seriously Impinges Upon an Individual's Fundamental Rights.

Maryland follows "the universally recognized rule that a physician, treating a mentally competent adult under non-emergency circumstances, cannot properly undertake to perform surgery or administer other therapy without the prior consent of his patient." *Sard v. Hardy*, 281 Md. 432, 439, 379 A.2d 1014, 1019 (1977). "The fountainhead of the doctrine * * * is the patient's right to exercise control over his own body, * * * by deciding for himself whether or not to submit to the particular therapy." *Id.* "A corollary to the doctrine is the patient's right, in general, to refuse treatment and to withdraw consent to treatment once begun." *Mack v. Mack*, 329 Md. 188, 210, 618 A.2d 744, 755 (1993).

Specifically, in the mental health context, Maryland courts have held that "[a] person's right to resist forcible administration of medications implicates a constitutionally protected liberty interest." *Baer v. Baer*, 128 Md. App. 469, 480, 738 A.2d 923, 929 (1999). Forced medication is particularly invasive of an individual's liberty and fundamental rights because antipsychotic drugs "alter the chemical balance in a patient's brain." *Williams v. Wilzack*, 319 Md. 485, 503, 573 A.2d 809, 817 (1990) (citations omitted).

Thus, under well-settled Maryland law, a mentally ill person—just like any other competent person—may refuse any "treatment or even cure if it entails what for him are intolerable consequences or risks, however warped or perverted his sense of values may be in the eyes of the medical profession, or even of the community, so long as any distortion falls short of what the law regards as incompetency." *Baer*, 128 Md. App. at 481, 738 A.2d 929, citing *United States v. Charters*, 829 F.2d 479, 495 (4th Cir. 1987).[2]

B. Absent a Specific Finding to the Contrary, Committed Individuals Remain Competent to Make Treatment Decisions.

1. Maryland Law Presumes Competence.

Maryland law also makes clear that involuntary commitment to a mental institution does not render an individual incompetent to make decisions about his or her own treatment. Indeed, "[t]he law of Maryland presumes that adults are competent to make their own informed decisions, and this presumption of competency does not disappear upon an involuntary admission to a mental health facility for psychiatric treatment, absent a proper determination otherwise." *Beeman v. Dep't of Health & Mental Hygiene*, 107 Md. App. 122, 146, 666 A.2d 1314, 1325 (1995) (citing Md. Code Ann., Health-Gen. § 5-601(f)); *accord, Williams*, 319 Md. at 509 n.8, 573 A.2d at 820 n.8

---

[2] Maryland's law on this subject is in accord with a federal agency's view on antipsychotic drugs as a "treatment option." The National Council on Disability, an independent federal agency mandated to make recommendations to the President and Congress on Disability Issues, has recommended that forced drugging "should be viewed as inherently suspect and incompatible with the principles of self-determination." National Council on Disability, From Privileges to Rights: People Labeled with Psychiatric Disabilities Speak for Themselves (2000), http://www.ncd.gov/newsroom/publications/2000/privileges.htm.

(1990). Consequently, the State must overcome this presumption if it wishes to override the treatment preferences of an individual in a non-emergency situation such as that contemplated by Section 10-708(g).[3]

Maryland's presumption of competency is consistent with state law across the country. There has been a "nearly unanimous modern trend in the courts, and among psychiatric and legal commentators, * * * to recognize that there is no significant relationship between the need for hospitalization of mentally ill patients and their ability to make treatment decisions." *Rivers v. Katz*, 495 N.E.2d 337, 342 (N.Y. 1986) (footnotes omitted); *see, e.g., Edward W. v. Lamkins*, 99 Cal. App. 4th 516, 533 (2002) ("psychiatric patients may not be presumed incompetent solely on the basis of their hospitalization"); *Steele v. Hamilton County Cmty. Mental Health Bd.*, 736 N.E.2d 10, 20 (Ohio 2000) ("it is clear that mental illness and incompetence are not one and the same"); *State v. Gerhardstein*, 416 N.W.2d 883, 895 (Wis. 1987) (striking down statute allowing forced medication of committed individuals as unconstitutional; concluding "no corollary" between "dangerousness and mental incompetence to make decisions regarding drug therapy" exists).[4]

---

[3] This would be a different case if the proceedings below had included a finding that Mr. Kelly was incompetent to make decisions about his course of treatment. As the record stands, however, no such allegation or finding was made by the Clinical Review Panel, the ALJ, or by any court, and neither the State nor its supporting *amici* contend here that Mr. Kelly is incompetent to make treatment decisions.

[4] The presumption of competency exists even when an individual has been determined to be not criminally responsible for reasons of mental illness or incompetent to stand trial. *See Williams*, 319 Md. at 487-91, 573 A.2d at 810–11; *United States v.*

2. Psychological Studies Validate Maryland's Presumption.

Maryland's presumption of competency also reflects accepted psychological research which recognizes that a mentally ill individual may remain competent and that an individual may be incompetent in some respects, but not in others. Mental illness is highly selective, typically damaging some areas of functioning while leaving others unimpaired.[5] Thus, an individual may be incompetent to stand trial, yet remain competent to make treatment decisions.[6] Clinical evidence suggests that, despite alterations in thinking and mood, psychiatric patients are not less capable than others of making health care decisions.[7]

Investigations of the competence levels of hospitalized patients with mental illness as compared with those of physically ill hospitalized patients and a control population of non-ill, non-hospitalized individuals reveal that most mentally ill patients are competent to make treatment decisions. One study measured competence based on four factors that, in some combination, comprise legal standards of competency in most states: (1) ability

---

Charters, 829 F.2d 479, 495 (4th Cir. 1987) ("The fact that [the defendant] has been found incompetent to stand trial is not dispositive of his medical competency.").

[5] Thomas Grisso & Paul S. Appelbaum, Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Health Professionals 19 (1998).

[6] David M. Siegal *et al.*, *Old Law Meets New Medicine: Revisiting Involuntary Psychotropic Medication of the Criminal Defendant*, 2001 Wis. L. Rev. 307, 358-59 (2001).

[7] Grisso & Appelbaum, *Assessing Competence to Consent to Treatment*, *supra*, at 19; Barbara Stanley *et al.*, *Preliminary Findings on Psychiatric Patients as Research participants: A Population at Risk?*, 138 Am. J. Psychiatry 669, 671 (1981) (finding mentally ill population to be as competent to make treatment decisions as comparable medically ill population).

to communicate a choice; (2) ability to understand relevant information; (3) ability to appreciate the situation and its likely consequences; (4) ability to manipulate information rationally.[8] When taking all measures into account, a vast majority of committed patients were legally competent. Accordingly, the study concluded "the justification for a blanket denial of the right to consent to or refuse treatment for persons hospitalized because of mental illness cannot be based on the assumption that they uniformly lack decision-making capacity."[9]

II. The Forced Administration of Antipsychotic Drugs Is Not Always of Therapeutic Value and Creates Substantial Risk to the Patient.

As Maryland courts have recognized, the forced administration of antipsychotic drugs is a highly intrusive invasion of personal and bodily integrity. Once in the patient's bloodstream, antipsychotic drugs dramatically alter that individual's physical, mental, and emotional state. "[T]he impact of the chemicals upon the brain is sufficient to undermine the foundations of personality." *In re Guardianship of Richard Roe, III,* 421 N.E.2d 40, 53 (Mass. 1981). If the benefits of such treatment were incontestable, as the State and its *amici* suggest,[10] it might be easy to decide that the General Assembly had

---

[8] Paul S. Appelbaum & Thomas Grisso, *The MacArthur Treatment Competence Study. I: Mental Illness and Competence to Consent to Treatment*, 19 Law & Hum. Behav. 105, 109 (1995).

[9] Thomas Grisso & Paul S. Appelbaum, *The MacArthur Treatment Competence Study. III: Abilities of Patients to Consent to Psychiatric and Medical Treatments*, 19 Law & Hum. Behav. 149, 171 (1995).

[10] The State does not even mention the potential devastating side effects of antipsychotic drugs in its brief. Its *amici* only state in passing that the "benefits outweigh

authorized such treatment for involuntarily committed patients whenever a Clinical Review Panel determines that it is medically appropriate (leaving aside the constitutional issues that would arise from such an interpretation). As we show below, however, there is legitimate controversy over the efficacy of treatment with antipsychotic drugs, especially when that treatment is administered against a patient's will.[11] In addition, antipsychotic drugs can produce devastating side effects that can outweigh whatever benefit the drugs provide.

A. Antipsychotic Drugs Do Not Work For All Psychiatric Patients.

The State and its *amici* present antipsychotic drugs as what are virtually miracle cures for all psychiatric illnesses, including the disease Mr. Kelly allegedly presents: delusional disorder. But while antipsychotic drugs are often effective in alleviating the psychotic symptoms of mental disorders, "a substantial minority of patients do not benefit from such drugs."[12] Recent research also indicates that antipsychotic drugs fail

---

the risks," without describing the risks. Brief of the Maryland Psychiatric Society *et al.* as *Amici Curiae* at 8.

[11] Indeed, even in cases where a state seeks to forcibly medicate an individual to restore competence to stand trial, as permitted under specified circumstances in *United States v. Sell*, 539 U.S. 166 (2003), clinicians argue that, because of the potential side effects and questionable efficacy of drugs, it is "much more clinically appropriate" to treat the mental illness without forcible medication "in a way that preserves dignity and self-respect." Terri Watters, *Competence to Stand Trial with Forced Medication: Placing Defendants in Harm's Way*, 5 J. Forensic Psychol. Prac. 79, 86 (2005).

[12] Brief for American Psychological Association as *Amicus Curiae* in *Sell v. United States*, 539 U.S. 166 (2003), 2002 WL 31898300, at *15–*16 (U.S. Dec. 19, 2002), citing Philip Janicak et al., *Principles and Practices of Psychopharmacotherapy* 110-133 (2d ed. 1997) and Bruce J. Winick, The Right to Refuse Mental Health Treatment 70 (1997).

to effectively treat a substantial percentage of patients with delusional disorder or, indeed, any percentage of patients with certain types of delusional disorder.

A very recent (2006) and comprehensive twelve-year survey of published reports on the treatment of delusional disorder with antipsychotic drugs found that very little clinical research on the effects of antipsychotic drugs on delusional disorder has been conducted.[13] That comprehensive review concluded that, in the cases and trials conducted, less than 50 percent of patients with delusional disorder were effectively treated with antipsychotic agents.[14]

That study also revealed that certain types of delusional disorder were more amenable to treatment by medication than others. For example, while individuals with somatic disorder reported some positive outcomes, *absolutely no studies* reported a single individual who had "recovered" by way of medication from persecutory or grandiose delusions[15]—the two subtypes of delusional disorder with which Mr. Kelly was diagnosed.[16]

---

[13] Theo C. Manschreck & Nealia L. Khan, *Recent Advances in the Treatment of Delusional Disorder*, 51 Can. J. Psychiatry 114 (2006).

[14] *See id.* at 117, Table 3a (49.3 percent).

[15] Delusions of the grandiose subtype center around the idea of having a great talent, importance, or unique insight. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders § 297.1 at 325 (4th ed. Text Revision 2000) (DSM-IV-TR). Delusions of the persecutory type are focused on the belief that the patient is being followed, misled, spied upon, or conspired against. *Id.*

[16] Manschreck & Khan, *supra*, 51 Can. J. Psychiatry at 117, Table 3b.

Another 2006 study's findings validate the twelve-year survey's conclusion that a lack of evidence supporting the treatment of delusional disorder with antipsychotic drugs exists. That study—written by proponents of antipsychotic drugs—noted that "there is not a single randomized, controlled psychopharmacological trial for treating [delusional disorder]" for a treating clinician to rely on when prescribing antipsychotics for delusional disorder.[17] Accordingly, the study concluded that the lack of evidence-based guidelines and "the emergent and disconcerting side-effects of the most commonly prescribed antispychotics" make it "particularly difficult" to "argue before the judge the need to force a person with delusional disorder to take [antipsychotic drugs]."[18]

Other advocates of medication for treatment of delusional disorder with drugs agree, conceding that a treating psychiatrist "cannot testify based on empirical research alone that the medicine will, more likely than not, be efficacious."[19] Moreover, they concede that only "meager or tangential" evidence exists that medication has been helpful in specific cases.[20]

Given the dearth of conclusive empirical research demonstrating that antipsychotic drugs effectively treat delusional disorder, it is not surprising that the State's *amici*

---

[17] Douglas A. Smith & Peter F. Buckley, *Pharmacotherapy of Delusional Disorders in the Context of Offending and the Potential for Compulsory Treatment*, 24 Behav. Sci. & L. 351, 351 (2006).

[18] *Id.* at 363.

[19] Alan R. Felthous *et al.*, *Are Persecutory Delusions Amenable to Treatment?*, 29 J. Am. Acad. Psychiatry & L. 461, 467 (2001).

[20] *Id.*

selectively cite the conclusion of a single authority in support of their position. That authority predates the 2006 study cited above, and its conclusion does not purport to be a systematic, comprehensive review of all the pertinent studies, nor does it take into account delusional subtypes. Moreover, the conclusion is extracted from a book in which the author repeatedly acknowledges the lack of reliable research supporting the efficacy of drugs for treating delusional disorders.[21]

In light of the lack of empirical evidence supporting the use of antipsychotic drugs to treat delusional disorder, it is not startling that the Eighth Circuit concluded that evidence did not support an order allowing forced medication to "treat" delusional disorder. In *United States v. Ghane*, 392 F.3d 317 (8th Cir. 2004), the government sought to involuntarily medicate a criminal defendant in order to render him competent to stand trial, which is permitted in certain circumstances by *United States v. Sell*, 539 U.S. 166 (2003). The magistrate judge conducted the type of hearing mandated by *Sell* and ordered forced medication. *Ghane*, 392 F.3d at 318. The *Sell* factor at issue in the appeal was whether the involuntary administration of antipsychotic medication was substantially likely to render the defendant competent to stand trial. *Id.* at 319. The Eighth Circuit concluded that it was not and that the magistrate's order requiring forced medication was clear error because the facts found by the magistrate showed that "'[d]elusional disorder

---

[21] Alistair Munro, Delusional Disorder: Paranoia and Related Illnesses 227 (1999). *See, e.g., id.* at 236 ("[t]here is very little scientific evidence to support pimozide or any other specific medication's particular effectiveness in delusional disorder.") and at 240 ("Treatment aspects of delusional disorder are in crying need of good, experimentally-based drug trials.").

resists treatment by both psychotherapy and antipsychotic medication'"; that "'[a]ntipsychotic medication is * * * ineffective at treating delusional disorder'"; and that "'[n]inety percent of delusional disorder patients do not experience improvement with treatment.'" *Id.* at 319–20. Thus, the court concluded that "[w]e cannot accept that a 'glimmer of hope' for [the defendant's] restored competence rises to the level of 'substantial likelihood,' as mandated by the Supreme Court's holding in *Sell*." *Id.* at 320.[22]

In sum, antipsychotic drugs are not the panacea for delusional disorder that they are portrayed to be by the State's and its *amici*'s briefs. Real questions exist regarding the efficacy of antipsychotic drugs to treat delusional disorder. Moreover, the lack of effectiveness must also be considered in conjunction with the potentially catastrophic side-effects of antipsychotic drugs, to which we now turn.[23]

B. The Potential Adverse Effects of Antipsychotic Drugs Can Outweigh Any Potential Benefits.

Antipsychotic drugs are capable of generating a wide variety of debilitating and detrimental adverse effects, even when prescribed and administered correctly. Any

---

[22] Mr. Ghane was later restored to competency despite the Court's refusal to forcibly medicate him. *See U.S. v. Ghane*, No. 03-00171-01-CR-W-ODS, 2006 U.S. Dist. LEXIS 34483, 2006 WL 1522674 (W.D. Mo. May 30, 2006).

[23] Other treatment options for delusional disorder, including Cognitive-Behavioral Therapy, Psychodynamic Therapy, and Supportive Therapy, are not even mentioned in the State's or its *amici*'s briefs. *See* Sara P. Silva *et al.*, *To Believe or Not to Believe: Cognitive and Psychodynamic Approaches to Delusional Disorder*, 11 Harv. Rev. Psychiatry 20 (2003); Theo C. Manschreck, *Delusional Disorder and Shared Psychotic Disorder*, *in* 1 Kaplan & Sadock's Comprehensive Textbook of Psychiatry § 13.2 at 1262 (2000).

benefit that a patient may derive from taking antipsychotic agents may be outweighed by the potential adverse effects that the drugs may produce.

Antipsychotic drugs, particularly conventional antipsychotics, such as haloperidol, may cause the development of very serious movement disorders, referred to as "extrapyramidal side effects." Extrapyramidal side effects include tardive dyskinesia, akathisia, and drug-induced parkinsonism. Tardive dyskinesia is a potentially irreversible disorder "characterized by involuntary, rhythmic, and often grotesque movements of the face, lips, tongue, fingers, hands, legs, and pelvis."[24] These symptoms of tardive dyskinesia may remain long after the patient has discontinued the use of antipsychotics. The involuntary and grotesque nature of the movements associated with the syndrome can make it a fully debilitating social impediment that may cause assimilation into the community to be extremely difficult for patients. Though current research suggests that tardive dyskinesia may stabilize, and occasionally improve, over time in some patients, the devastating effects of this illness render its consideration critical in making the decision to administer antipsychotics.[25]

---

[24] Robert M. Levy & Leonard S. Rubenstein, The Rights of People with Mental Disabilities 112 (1996); Rafael A. Rivas-Vasquez *et al.*, *Atypical Antipsychotic Medications: Pharmacological Profiles and Psychological Implications*, 31 Prof. Psychol.: Res. & Prac. 628, 630 (2000).

[25] John Wilkaitis, *et al.*, *Chapter 27: Classic Antipsychotic Medications*, *in* The American Psychiatric Publishing Textbook of Psychopharmacology 425, 437 (Alan F. Schatzberg & Charles B. Nemeroff, eds., 3rd ed., 2004).

One of the most common extrapyramidal side effects caused by the use of antipsychotic drugs is akathisia, which affects between 20 and 25 percent of patients on conventional antipsychotics.[26] "Subjectively, akathisia consists of an intense feeling of dysphoria and extreme anxiety, as occurs with panic attacks. Objectively, it is associated with observed physical restlessness and an inability to sit still."[27] The condition, which may occur at any time during treatment, can cause patients to feel irritable or agitated and may increase suicidal or aggressive behavior.[28] It is often difficult for patients to describe the symptoms of akathisia, making it all the more likely for clinicians to fail to diagnose the condition or to attribute its effects to the underlying psychiatric illness.[29]

Another common extrapyramidal side effect is parkinsonism, which refers to the drug-induced development of Parkinson's disease-like symptoms, including muscle stiffness, tremor, and a shuffling gait.[30] Parkinsonism can also cause drooling, cogwheel rigidity, loss of spontaneous and associated movements, blank stare, dulled facial

---

[26] K.N. Roy Chengappa & Patrick Flynn, *Chapter 12: Akathisia*, *in* Drug-Induced Dysfunction in Psychiatry 153, 153 (Mathcheri S. Keshavan & John S. Kennedy, eds., 1992).

[27] Arshia A. Shirzadi & S. Nassir Ghaemi, *Side Effects of Atypical Antipsychotics: Extrapyramidal Symptoms and the Metabolic Syndrome*, 14 Harv. Rev. Psychiatry 152, 157 (2006).

[28] Wilkaitis *et al.*, *supra*, at 437.

[29] Shirzadi & Ghaemi, *supra*, at 157.

[30] Wilkaitis *et al.*, *supra*, at 437.

expressions, and stooped posture.[31] Although these symptoms are usually reversible, they can be extremely unpleasant and occur in about 15 percent of patients receiving conventional antipsychotic drugs.[32]

Antipsychotic drugs can also cause an occasionally fatal neurological disorder called neuroleptic malignant syndrome. The characteristics of this syndrome include severe muscular rigidity, high fever, tachycardia, hypertension, and changing levels of consciousness.[33] Though neuroleptic malignant syndrome appears in only a small percentage of patients receiving antipsychotic drugs, its fatality rate has been estimated to be between 10 and 20 percent,[34] with some estimates placing it as high as 30 percent.[35]

Conventional antipsychotic drugs, including haloperidol, have also been demonstrated to cause sudden death and agranulocytosis. Agranulocytosis, a serious blood disorder which leads to a decrease in an individual's white blood cell count, can place patients at increased risk for contracting life-threatening infections and is associated with a mortality rate as high as 30 percent.[36] There is also evidence that the risk of

---

[31] Robert M. Julien, *A Primer of Drug Action* 230–31 (6th ed. 1992); Shirzadi & Ghaemi, *supra*, at 155.

[32] Wilkaitis *et al.*, *supra*, at 437.

[33] *Id.*

[34] Gerard Addonizio, *Chapter 11: Neuroleptic Malignant Syndrome*, *in* Drug-Induced Dysfunction in Psychiatry 145, 148 (Matcheri S. Keshavan & John S. Kennedy, eds., 1992).

[35] Wilkaitis *et al.*, *supra*, at 437.

[36] *Id.* at 438.

sudden death is more than two times greater for patients receiving conventional antipsychotic drugs than for nonusers.[37]

A new class of antipsychotic drugs was developed in the early 1990s. This class, referred to as atypical antipsychotics, appears to cause a lower incidence of extrapyramidal side effects than conventional antipsychotics do. However, atypical antipsychotics, including risperidone, quetiapine, and olanzapine, are not without adverse effects. The Food and Drug Administration continues to warn of the possibility of atypical antipsychotics causing tardive dyskinesia and neuroleptic malignant syndrome, as well as other serious negative side effects.[38] Of greatest concern is the propensity of atypical antipsychotic drugs to cause metabolic disorders, including drastic weight gain and the onset of diabetes mellitus.[39] Severe weight gain and obesity have the independent potential to generate serious health concerns that should not be taken

---

[37] Alexander H. Glassman & J. Thomas Bigger, Jr., *Antipsychotic Drugs: Prolonged QTc Interval, Torsade de Pointes, and Sudden Death*, 158 Am. J. Psychiatry 1774, 1779 (2001).

[38] U.S. Food & Drug Admin., *Patient Information Sheet: Olanzapine (marketed as Zyprexa)* (2005), http://www.fda.gov/cder/drug/InfoSheets/patient/olanzapinePIS.htm; U.S. Food & Drug Admin., *Patient Information Sheet: Risperidone Tablets (marketed as Risperdal)* (2005), http://www.fda.gov/cder/drug/InfoSheets/patient/risperidonePIS.htm; U.S. Food & Drug Admin., *Patient Information Sheet: Quetiapine Tablets (marketed as Seroquel)* (2005), http://www.fda.gov/cder/drug/InfoSheets/patient/quetiapinePIS.htm. *See also* Shirzadi & Ghaemi, *supra*, at 152 (noting that "real-world experience suggests that extrapyramidal symptoms (EPS) are still a concern with regard to [atypical antipsychotics].").

[39] Jenna Griffiths & Pascale Springuel, *Atypical Antipsychotics and Impaired Glucose Metabolism*, 15 World Health Org. Drug Info. 152, 152–154 (2001), http://www.who.int/druginformation/vol15num3_4_2001/vol15-3_4.pdf.

lightly.[40] Diabetes is also an acute and irreversible disease that requires extreme lifestyle changes and is associated with long-term health complications.[41] The risk of metabolic abnormalities is considered relatively high with the use of olanzapine, and intermediate with risperidone and quetiapine.[42] A 1999 study of patients with schizophrenia being treated with antipsychotic drugs found that these patients were nearly eight times more likely to have diabetes mellitus than their comparable general population group, and that patients receiving atypical antipsychotic drugs were nine percent more likely to have diabetes than those patients receiving conventional antipsychotic drugs.[43] The Food and Drug Administration has also issued a Public Health Advisory warning that the use of atypical antipsychotic drugs is associated with increased mortality rates in elderly

---

[40] "Obesity is a known risk factor for hypertension, elevated triglycerides, insulin resistance, and diabetes mellitus. * * * Even modest increases in BMI (>1.0) show a positive linear correlation with increased mortality from cardiovascular disease." Shirzadi & Ghaemi, *supra*, at 158. "In the general population excess weight increases the risk of hypertension, coronary artery disease, stroke, osteoarthritis, sleep apnoea, type II diabetes mellitus and several cancers including endometrial, breast, prostate and colon cancer." Peter Haddad, *Weight Change with Atypical Antipsychotics in the Treatment of Schizophrenia*, 19 J. Psychopharmacology 16, 17 (Supp. 2005).

[41] *See* N.R. Kleinfield, *In Diabetes, One More Burden for the Mentally Ill*, N.Y. Times, June 12, 2006, at A1.

[42] George M. Simpson, *Atypical Antipsychotics and the Burden of Disease*, 11 Am. J. Managed Care S235, S236 (Supp. 2005).

[43] Michael J. Sernyak, *et al.*, *Association of Diabetes Mellitus with Use of Atypical Neuroleptics in the Treatment of Schizophrenia*, 159 Am. J. Psychiatry 561, 561, 565 (2002).

patients with dementia.[44] Thus, although atypical antipsychotics appear to have a lower risk of extrapyramidal side effects, they have not ameliorated the risk altogether, and have generated a new set of problematic adverse effects not previously seen with conventional antipsychotics.

In addition to these very serious adverse effects, patients taking atypical antipsychotics can, and often do, experience dizziness, increased heart beat, seizures, differences in body temperature, constipation, nausea, vision changes, liver problems, sleepiness, restlessness, low blood pressure, and dry mouth.[45] These adverse effects, though comparably moderate, can considerably affect the daily lives of patients and "can be a source of acute distress to patients who are struggling to feel wide awake and think more clearly" in order to work through their disorders.[46]

Given these potential adverse effects, it comes as little surprise that Maryland Courts, and courts across the country, have repeatedly acknowledged the dangerous side effects of administering antipsychotic drugs. *See, e.g., Washington v. Harper*, 494 U.S. 210, 239 (1990) (antipsychotic drugs "can cause irreversible and fatal side effects"); *Williams*, 319 Md. at 503, 573 A.2d at 817 n.6 (citing *Washington*); *Myers v. Alaska Psychiatric Institute*, 138 P.3d 238, 241 (Alaska 2006) ("psychotropic drugs* * * are

---

[44] U.S. Food & Drug Admin. Public Health Advisory, *Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances* (2005), http://www.fda.gov/cder/drug/advisory/antipsychotics.htm.

[45] See the U.S. Food and Drug Administration Patient Information Sheets cited in note 38.

known to cause a number of potentially devastating side effects."); *Large v. Superior Court*, 714 P.2d 399, 403 (Ariz. 1986) (extensively discussing side effects of antipsychotic drugs, including extrapyramidal side effects and tardive dyskinesia).

In sum, the risk of side effects from antipsychotic drugs is significant and severe. The risks are further compounded by the lack of concrete data regarding the efficacy and side effect profiles of antipsychotic drugs in the treatment of delusional disorder specifically. Though much literature exists on the use of antipsychotic agents to treat schizophrenia, delusional disorder is a separate and distinct condition, and the comparative absence of research on the treatment of this disorder generates further skepticism about the forced use of antipsychotic drugs.[47] As explained in Part II.A. above, there is not a single randomized, controlled psychopharmacological study regarding the treatment of delusional disorder.[48] The lack of research and data has generated considerable gaps in knowledge concerning the treatment of this disorder and, "in the absence of a robust literature, most clinicians rely on their experience and guidelines for treating schizophrenia when treating patients with delusional disorder."[49] The adverse effects of antipsychotic agents are a significant source of concern for clinicians in the treatment of schizophrenia, despite the fact that efficacy for such illness

---

[46] Levy & Rubenstein, *supra*, at 112.

[47] Felthous *et al.*, *supra*, 29 J. Am. Acad. Psychiatry & L. at 461, 465.

[48] Smith & Buckley, *supra*, 24 Behav. Sci. & L. at 351.

[49] *Id.*

is generally well-established.[50] "This risk-benefit profile is likely to be more precarious in delusional disorder, where efficacy has not been adequately established."[51] Furthermore, there is a lack of long-term follow-up data regarding the use of atypical antipsychotics in the treatment of acute psychoses, making the adverse effects of such drugs even more uncertain.[52] Weighing the potential costs with the uncertain benefits of antipsychotic drugs is a difficult and deeply personal decision for any patient, making the patient's informed consent of paramount importance.

C. Forced Medication Can Undermine Effective Treatment.

The State argues that, without the forced administration of drugs, a committed individual does not receive the "benefit of treatment to which he is entitled" and "will never be well enough for discharge". State's Brief at 18. And the State's *amici* argue that a "substantial risk of indefinite continued hospitalization" exists if Section 10-708 is not interpreted to allow for "treatment" through the forced medication of competent individuals. Brief for the Maryland Psychiatric Society *et al.* as *Amici Curiae* at 9. But, in fact, researchers—even those in favor of the use of drugs to treat delusional disorder—agree that therapeutic alliances are key for treatment to be effective and can be jeopardized by the forced administration of drugs. Moreover, research shows that, in many cases, individuals who refuse drugs do not persist in their refusal, that refusal itself

---

[50] *Id.* at 358.

[51] *Id.*

[52] *Id.*

and the ensuing negotiation can be therapeutically valuable, and that allowing competent individuals to refuse treatment does not lead to the warehousing of patients without treatment.

1. Therapeutic Alliances Are Essential to Treatment.

Therapeutic alliances—the special relationships between patients and their therapists or psychiatrists—are central to the effective treatment of mental illnesses.[53] Fundamental to the successful treatment of delusional disorder, for example, "is an effective and therapeutic doctor-patient relationship, which is far from easy to establish."[54] Given that non-bizarre delusions are characteristic of delusional disorder, "it is unlikely that there is any psychiatric condition that requires greater diplomacy, openness, and reliability from the therapist."[55] Even when antipsychotic drugs are employed, "skillful negotiate[ion]" is required for effective treatment because the symptomatic denial of problems, coupled with the adverse effects of drugs, undermine compliance.[56] "Skillful negotiat[ion]" simply does not exist when drugs are administered against a patient's will. Accordingly, even advocates of the use of drugs to treat

---

[53] Rosemarie McCabe & Stefan Priebe, *The Therapeutic Relationship in the Treatment of Severe Mental Illness: A Review of Methods and Findings*, 50 Int'l J. Soc. Psychiatry 115, 115 (2004).

[54] Manschreck, *Delusional Disorder and Shared Psychotic Disorder*, *supra*, at 1262.

[55] *Id.*

[56] Theo C. Manschreck, *Delusional Disorder: The Recognition and Management of Paranoia*, 57 J. Clinical Psychiatry 32, 37 (1996).

delusional disorder admit that forcibly medicating a patient can jeopardize an already perilous therapeutic relationship and undermine long-term treatment.[57]

2. The Act of Refusal Can Have Therapeutic Advantages.

While ignoring a patient's choice can have devastating effects on a treatment alliance, patient drug refusals can actually serve to strengthen this alliance. When mental health professionals view a patient's refusal as a chance to communicate with the patient about the patient's medication and condition, drug refusal can be resolved to the advantage of all parties involved. In fact, after studying drug refusers, Dr. Paul Appelbaum, a prominent proponent of involuntary medication, concluded: "Not only is permitting limited refusal generally innocuous, but some definite gains may accrue from the accompanying negotiations."[58]

In addition to these immediate treatment benefits, a therapeutic alliance characterized by respect and communication can produce positive results that outlast institutionalization, and this effect can be critical for long-term treatment success. Patients who exercise their right to refuse and participate assertively in their own treatment are more likely to succeed outside the hospital environment as independent members of the community. Studies have shown that compliance with antipsychotic medication is enhanced by increased doctor-patient communication and negotiation.

---

[57] Smith & Buckley, *supra*, 24 Behav. Sci. & L. at 361, 363.

[58] Paul S. Appelbaum & Thomas G. Gutheil, *Drug Refusal: A Study of Psychiatric Inpatients*, 137 Am. J. Psychiatry 340, 345 (1980).

"Patient involvement in decisions about medication * * * is critically important to compliance."[59]

A study comparing in-hospital and post-hospital treatment outcomes of refusers and compliers revealed that, overall, these two groups were "remarkably similar in all important outcome measures."[60] The two groups differed significantly, however, in their ability to cope outside the hospital environment. Readmitted refusers had functioned in the community twice as long as readmitted compliers.[61] Moreover, even patients who had refused and later consented to treatment fared better outside the hospital than those who never refused.[62] The researchers suggested that "a healthy skepticism about doctors, medicine and psychiatry and some sense of themselves as not without power and control over their lives * * * may have helped the 'refusers' to better cope with life outside the hospital.

Thus, these findings show that the supposed "substantial risk of indefinite continued hospitalization" without forced medication asserted by State's *amici* does not survive scrutiny; in fact, refusals may lead to better long-term treatment outcomes. See Brief for the Maryland Psychiatric Society *et al.* as *Amici Curiae* at 9. Moreover, the

---

[59] Ronald J. Diamond, *Enhancing Medication Use in Schizophrenic Patients*, 44 J. Clinical Psychiatry 7, 14 (1983).

[60] Irwin N. Hassenfeld & Barbara Grumet, *A Study of the Right to Refuse Treatment*, 12 Bull. Am. Acad. Psychiatry & L. 65, 68 (1984).

[61] *Id.*

[62] *Id.*

very study of drug refusers cited in support of the *amici's* dire warning concludes that: "Our findings do not support frequently voiced concerns that legal protection of patients' right to refuse would reduce psychiatric institutions to primarily custodial functions; to the contrary, we found that most patients will receive needed treatment even if they initially refuse it."[63]

Accordingly, construing Section 10-708 to prohibit forced medication of competent individuals will not necessarily compromise their treatment. Therapeutic alliances—which are essential to effective treatment—are undermined by the use of forced medication. Thus, forced medication can actually work at cross purposes with the goal of providing effective treatment, and allowing patients to refuse does not inevitably lead to their indefinite hospitalization.

CONCLUSION

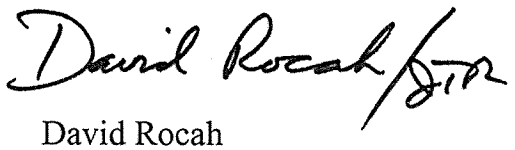
Contrary to the State's assertions, the idea that the Maryland legislature, through Section 10-708, would prohibit "treating" individuals against their will with powerful drugs with potentially devastating side effects does not defy common sense or logic. Indeed, that skepticism would be in accord with Maryland's recognition of the right of competent individuals—including those committed to institutions—to make their own treatment decisions. As we have shown, the efficacy of antipsychotic drugs to treat delusional disorder has not been conclusively established, and potentially devastating

---

[63] Steven K. Hoge *et al.*, *A Prospective, Multicenter Study of Patients' Refusal of Antipsychotic Medication*, 47 Archives Gen. Psychiatry 949, 955 (1990).

side effects can result. Moreover, the very goal espoused by the State—effective treatment leading to release—can be undermined by forced medication. In sum, Appellee's interpretation of Section 10-708 is consistent with sound policy that will not result in disastrous consequences for involuntarily committed patients.

Respectfully submitted,



David Rocah
American Civil Liberties
Union Foundation of Maryland
3600 Clipper Mill Rd.
Suite 350
Baltimore, MD 21211
(410) 889-8555

John Townsend Rich*
Melissa Briggs Hutchens*
Goodwin Procter LLP
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 346-4000

*Not admitted in Md., motions for special admission pending

September 1, 2006

Pursuant to Maryland Rule 8-504(a)(8), this brief has been prepared with proportionately spaced type: Times New Roman 13 point

CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of August 2006, two copies of the Brief for the American Civil Liberties Union of Maryland *et al.* as *Amici Curiae* in Support of Appellant were mailed, first-class postage prepaid, to counsel for the parties at the following addresses:

The Honorable J. Joseph Curran, Jr.
Attorney General of Maryland
Kathleen A. Ellis
Assistant Attorney General
Tracee Orlove Fruman
Staff Attorney
Office of the Attorney General
300 West Preston St., Suite 302
Baltimore, MD 21201
Counsel for Appellant

Suzanne Sangree
Director of Appellate Advocacy
Public Justice Center
500 East Lexington Street
Baltimore, MD 21202
Counsel for Appellee

Laura Cain
Managing Attorney, Adult Mental Health
Irene Smith
Maryland Disability Law Center
1800 N. Charles Street—Suite 400
Baltimore, MD 21201
Counsel for Appellee

Melvin J. Sykes
120 E. Baltimore Street—Suite 1701
Baltimore, MD 20202-6701
Counsel for Amici Curiae Maryland Psychiatric Society et al.

David Rocah