IN THE
COURT OF APPEALS OF MARYLAND

No. 34
September Term, 2015

GARY ALLMOND, *Petitioner*,

v.

DEPARTMENT OF HEALTH AND MENTAL HYGIENE, *Respondent.*

On Appeal from the Circuit Court for Howard County
(Lenore R. Gelfman, Judge)
Pursuant to a Writ of Certiorari to the Court of Special Appeals

BRIEF FOR THE AMERICAN CIVIL LIBERTIES UNION OF MARYLAND, THE JUDGE DAVID L. BAZELON CENTER FOR MENTAL HEALTH LAW, MENTAL HEALTH ASSOCIATION OF MARYLAND (MHAMD), THE FREEDOM CENTER, ON OUR OWN OF MARYLAND, THE IMAGE CENTER FOR PEOPLE WITH DISABILITIES, AND THE MARYLAND OFFICE OF THE PUBLIC DEFENDER AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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September 29, 2015

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INTERESTS 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, including the right to refuse treatment by antipsychotic drugs.

Mental Health Association of Maryland (MHAMD) is a voluntary, nonprofit citizens' organization that brings together consumers, families, professionals, advocates and concerned citizens for unified action in all aspects of mental health and mental illness. Since 1915, MHAMD has been dedicated to promoting mental health, preventing mental disorders and achieving victory over mental illness through advocacy, education, research, and service. MHAMD is an affiliate of Mental Health America. MHAMD envisions a just, humane and healthy society in which all people are accorded respect, dignity and the opportunity to achieve their full potential free from stigma and prejudice. MHAMD supports person-centered recovery in the least restrictive environment, and opposes unnecessary restrictions on liberty, independence, choice and self-determination.

The Freedom Center, founded in 2001, is a Center for Independent Living that offers services and supports to empower people with disabilities to lead self-directed,

independent, and productive lives in a barrier-free community. Its services are designed to promote community integration among people with disabilities so they can fully participate in their own communities within their own homes, having equal opportunities to achieve independence as those without disabilities. As part of its efforts to advocate for independence and equal opportunity, the Center advocates for people with disabilities to be afforded the same choice and autonomy as others in making decisions about their treatment.

On Our Own of Maryland is a statewide mental health consumer education and advocacy group that promotes equality in all aspects of society for people who receive mental health services and develops alternative, recovery-based mental health initiatives. Since 1982, On Our Own has provided technical assistance to consumer groups, information and referral, and mental health systems monitoring and evaluation across Maryland. On Our Own advocates for mental health services that respect individual choices.

The IMAGE Center for People with Disabilities founded in 2011, provides skills, training, and advocacy services to people with disabilities in order for them to live independently in the community and be full contributors in their families, in the community, and on the job. By bringing new solutions to address difficult problems problems, the Center seeks to empower individuals to make their own decisions and make the challenging possible.

The Maryland Office of the Public Defender (OPD) provides legal representation to defendants who cannot afford to hire a private attorney without undue financial hardship. It represents the majority of individuals facing involuntary commitment to psychiatric hospitals. While its representation does not extend to involuntary medication panel hearings, individuals facing those proceedings are often simultaneously represented through the OPD for ongoing criminal and/or civil commitment matters. Gary Allmond is one such client. The level of continuing care of its mentally disabled clients is a matter of utmost concern to OPD. The manner in which they are treated in psychiatric hospitals has a direct and fundamental relation to the outcome of their criminal or civil commitment matters.

QUESTION PRESENTED

Whether Section 10-708(g) of the Health-General Article of the Maryland Code, as amended to permit the State to forcibly medicate involuntarily committed patients with mental illness who have elected to refuse treatment with antipsychotic drugs and who have neither been found incompetent to make treatment decisions about themselves nor to be a danger to himself or others in the institution, is unconstitutional under the Maryland Declaration of Rights.

STATEMENT OF THE CASE

Amici adopt the Statement of the Case in the Brief of Petitioner. Nevertheless, they believe it useful to summarize the essential facts to clarify the issue that this brief will address.

Mr. Allmond was committed to the Perkins institution in 2011 upon a finding that he was incompetent to stand trial on a murder charge in the Circuit Court for Baltimore City, pursuant to Section 3-106(b)(1) of the Criminal Procedure Article of the Code, which also required a finding that, because of mental retardation or a mental disorder, he was a danger to himself or to others. Mr. Allmond has never been found incompetent to make treatment decisions. After Mr. Allmond refused treatment with antipsychotic medications, his treatment team sought and received authorization to forcibly medicate Mr. Allmond pursuant to Section 10-708(g) of the Heath-General Article of the Code, which authorizes such treatment when "prescribed by a psychiatrist for the purpose of treating the individual's mental disorder," subsection (g)(1), when the administration of medicine "represents a reasonable exercise of professional judgment," subsection (g)(2), and when, without the medication, the individual is at "substantial risk of continued hospitalization," for various reasons, only some of which are at issue here, subsection (g)(3). Mr. Almond had a history of schizophrenia, and the treatment team sought and received authority to treat Mr. Allmond involuntarily with the psychotropic medications fluphenazine, haloperidol, olanzapine, and lorazepam, as well as diphenphydramine and

benztropine to mitigate the side effects of the antipsychotic drugs. Mr. Allmond appealed to an administrative law judge.

The Administrative Law Judge ruled that without the medications, Mr. Allmond was at substantial risk of continued hospitalization because he remained seriously mentally ill "with no significant relief of the mental illness symptoms that resulted in his being committed under * * * Title 3 of the Criminal Procedure Article" (E. 55),[1] a clear reference to treatment under subsection (g)(3)(i)(2): "[R]emaining seriously mentally ill with no significant relief of the mental illness symptoms that: [¶] 2. Resulted in the individual being committed to a hospital under this title or Title 3 of the Criminal Procedure Article."

For similar reasons, the Administrative Law Judge also ruled that without the medications, Mr. Allmond was "at substantial risk of continued hospitalization because of remaining seriously mentally ill for a significantly longer period of time with mental illness symptoms that * * * resulted in you being committed * * * under * * * Title 3 of the Criminal Procedural Article" (E. 56–57), a clear reference to treatment under subsection (g)(3)(ii)(2): "[R]emaining seriously mentally ill for a significantly longer period of time within the mental illness symptoms that: [¶] 2. Resulted in the individual being committed to a hospital under this title or Title 3 of the Criminal Procedure Article."

The Administrative Law Judge also specifically found that Mr. Allmond was not a danger to himself or others while in the hospital (E. 55), thus rejecting treatment under subsection (g)(3)(i)(1): "[R]emaining seriously mentally ill with no significant relief of the mental illness symptoms that: [¶] 1. Cause the individual to be a danger to the individual others while in the hospital", and under subsection (g)(3)(ii)(1) (containing similar words).

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[1] The judge also referred to commitment under Title 10 of the Health-General Article of the Code, but that was apparently because she was paraphrasing subsection (g)(3)(i)(2) of Section 10-708. While the grounds for commitment are not pertinent here, it is clear that Mr. Allmond was not committed under Title 10, but under Title 3 of the Criminal Procedure Article, Md. Code Ann., Crim. Proc. § 3-106(b)(1).

The Administrative Law Judge also stated that she could not find that, without the medications, Mr. Allmond would be a danger to himself or others if released from the hospital (E. 56), thus rejecting treatment under (g)(3)(i)(3): "[R]emaining seriously mentally ill with no significant relief of the mental illness symptoms that: [¶] 3. "Would cause the individual to be a danger to the individual or others if released from the hospital," and under subsection (g)(3)(ii)(3), containing similar words.[2]

Mr. Allmond petitioned for judicial review of the ALJ decision in the Circuit Court of Howard County on the grounds that Section 10-708(g), as amended, violates the U.S. Constitution and the Maryland Declaration of Rights.[3] That court heard argument on the petition, ruled that the statute constitutional, and affirmed the ALJ decision in a ruling from the bench.

SUMMARY OF ARGUMENT

Amici support Mr. Allmond's legal argument that the new statutory authorization for forcing committed individuals to take antipsychotic drugs when they are not a danger to themselves or others *in the hospital* is unconstitutional. Rather than repeating that argument, *amici* submit this brief to demonstrate the legitimacy of Mr. Allmond's concern about the potentially severe side effects of antipsychotic medications and the limited effectiveness of those medications. This concern, animating Mr. Allmond's desire to avoid the forced administration of these drugs, is not irrational, warped, or perverted, and is consistent with well-grounded concerns about the efficacy and dangers of antipsychotic drugs.[4] Indeed, there is some research indicating that these medications

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[2] The judge also found no evidence that Mr. Allmond was "at risk of relapsing into a condition in which you are unable to provide for your essential human needs of health and safety" (E. 57), thus rejecting treatment under subjection (g)(3)(iii): "Relapsing into a condition in which the individual is unable to provide for the individual's essential human needs of health or safety."

[3] We understand that Mr. Allmond subsequently dropped the argument that his treatment violated the U.S. Constitution.

[4] Mr. Allmond's brief argues (at 29) that "an individual's concerns with the severe side effects of antipsychotic medications and the uncertain efficacy of those medications does

are even less effective for individuals over 40 like Mr. Allmond and that the risks generally outweigh the benefits.

First, Maryland law recognizes that committed individuals remain able to make treatment decisions, absent a finding of incompetence, and that the forced administration of drugs seriously infringes upon an individual's fundamental rights. Second, antipsychotic drugs are not a panacea to mental illness. Research indicates that there are real questions regarding the efficacy of antipsychotic drugs to treat schizophrenia—the condition with which Mr. Allmond was diagnosed. Further, 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 and instituting a treatment regime that Mr. Allmond would voluntarily follow after release. While it may make sense for some individuals to be treated with antipsychotic drugs after consulting with a physician about the risks and benefits, it also makes sense that a competent individual would refuse such treatment, even at the risk of prolonging confinement.

STANDARD OF REVIEW

Amici adopt the statement of the standard of review in Petitioner's Brief.

ARGUMENT

I. The Maryland Declaration of Rights 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. The Maryland Declaration of Rights Recognizes That the Forced Administration of Antipsychotic 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 under-

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not demonstrate a 'warped or perverted sense of values,' and the choice not to take such medications is regarded by many as wise rather than foolish."

take 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 fountain-head 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).

Maryland's constitutional decisions are in accord with federal decisions making clear that an individual's right to make autonomous decisions about medical treatment is deeply rooted in our national heritage. *See, e.g., Sell v. United States*, 539 U.S. 166 (2003) ("[A]n individual has a 'significant' constitutionally protected liberty interest in 'avoiding the unwanted administration of antipsychotic drugs.'") (quoting *Washington v. Harper*, 494 U.S. 210, 221 (1990)); *Harper*, 494 U.S. at 237–38 ("The liberty of citizens to resist the administration of mind altering drugs arises from our Nation's most basic values.") (Stevens, J., concurring in part and dissenting in part); *United States v. Cruz*, 757 F.3d 372, 379 n.4 (3d Cir. 2014), *cert. denied*, 135 S. Ct. 1015 (2015) ("There are 'several dimensions' to that liberty [to resist forced medication], which 'are both physical and intellectual. Every violation of a person's bodily integrity is an invasion of his or her liberty * * *. And when the purpose or effect of forced drugging is to alter the will and the mind of the subject, it constitutes a deprivation of liberty in the most literal and fundamental sense.'") (quoting *Harper*, 494 U.S. at 237–38 (Stevens, J., concurring in part and dissenting in part)).

There is an unavoidable conflict between Maryland constitutional law and statutory law. Under well-settled Maryland constitutional 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). In contrast, Section 10-708(g) permits forced medication merely when there is a substantial risk of continued hospitalization. This brief demonstrates that, constitutional issues aside, the legislative decision that doctors should have the final say in deciding whether psychotropic drugs are appropriate for treating competent patients with mental health disorders—in this case, schizophrenia—gives determinative weight to decisions that would be based upon controversial and, at times, contradictory scientific evidence and permits doctors to override the patient's legitimate concerns about serious side effects.

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)[5]); *accord, Williams*, 319 Md. at 509 n.8, 573 A.2d at 820 n.8 (1990). This includes the right to refuse treatment, including medication. *Dep't of*

[5] Section 5-601(f) of the Health-General Article of the Code provides: "'Competent individual' means a person * * * who has not been determined to be incapable of making an informed decision."

Health & Mental Hygiene v. Kelly, 397 Md. 399, 418, 918 A.2d 470, 481 (2007). Consequently, the State must overcome this presumption if it wishes to override under Section 10-708(g) the treatment preferences of an individual who is not dangerous within the facility in which he or she is confined.

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., Scott S. v. Superior Court*, 204 Cal. App. 4th 326, 336 (2012) ("Our Legislature has made it very clear that the patient's right to agree to or refuse a recommended treatment does not vanish even when the patient is involuntarily committed."); *Rogers v. Comm'r of Dep't of Mental Health*, 458 N.E.2d 308, 314 (Mass. 1983) ("We conclude that a mental patient has the right to make treatment decisions and does not lose that right until the patient is adjudicated incompetent by a judge through incompetence proceedings.").[6]

This would be a different case if the proceedings below had included a finding that Mr. Allmond was incompetent to make decisions about his course of treatment, and we do not address how Section 10-708 would apply in the event of such a finding. As the record stands, however, no such allegation or finding was made by the Clinical Review Panel, the ALJ, or by any court, and the State has not contended that Mr. Allmond is legally or factually incompetent to make treatment decisions. Section 10-708(g) thus

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[6] 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. McAllister*, 225 F.3d 982, 989 (8th Cir. 2000) ("'Mentally ill patients, though incapacitated for particular purposes, can be competent to make decisions concerning their medical care [* * *],'" *quoting United States v. Charters*, 829 F.2d at 488); *Davis v. Hubbard*, 506 F. Supp. 915, 935 (N.D. Ohio 1980) (holding that "there is no necessary relationship between mental illness and incompetency which renders [the mentally ill] unable to provide informed consent to medical treatment").

potentially or in fact (as here) permits forced medication of individuals who are fully competent to make treatment decisions on their own.

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.[7] Thus, an individual may be incompetent to stand trial, yet remain competent to make treatment decisions.[8] Clinical evidence suggests that, despite alterations in thinking and mood, psychiatric patients are not less capable than others of making health care decisions.[9]

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 to communicate a choice; (2) ability to understand relevant information; (3) ability to appreciate the situation and its likely consequences; and (4) ability to manipulate information rationally.[10] When taking all measures into account, a vast majority of

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

[8] 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).

[9] 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).

[10] 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).

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."[11]

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). As we show below, psychiatric research studies have raised significant concerns about the effectiveness of antipsychotic drugs, especially when that treatment is administered against a patient's will.[12] In addition, antipsychotic drugs can produce devastating side effects that can be long-term and can outweigh whatever benefit the drugs provide.

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[11] 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). *See also* Paul S. Appelbaum, *Missing the Boat: Competence and Consent in Psychiatric Research*, 155 Am. J. Psychiatry 1486, 1487 (1998) (noting that one study demonstrated that "[with] repeated disclosure of information all 49 of the subjects with schizophrenia [in a study] were able to respond correctly to a lengthy series of questions about the research projects to which they were being asked to consent" and noting that other research teams have observed similar results).

[12] 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).

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

Antipsychotics are not miracle cures for all psychiatric illnesses, including the disease Mr. Allmond allegedly presents: schizophrenia. But while antipsychotic drugs are sometimes effective in alleviating the psychotic symptoms of mental disorders, a significant number of patients find that these drugs have limited efficacy and unbearable effects.

In a recent (2012) long-term study of the safety and effectiveness of certain "second-generation" antipsychotics (referred to in the medical community as "atypical antipsychotics") on patients over 40 (a study which included olanzapine, a drug with which the Perkins treatment team received authority to forcibly medicate Mr. Allmond), researchers reached the following striking conclusions: (1) long-term, there was "no significant change in psychopathology" for patients taking any of the antipsychotic drugs; (2) there was no significant improvement in patients' psychiatric outcomes or psychosis over a 6 month period; (3) and "the overall risk-benefit ratio for the atypical antipsychotics in patients over age 40 was not favorable, irrespective of diagnosis [(including schizophrenia)] and drug."[13] Noting that "the results of our study are sobering," the researchers concluded that "[s]hared decision making, involving detailed discussions with the patient . . . about the risks and benefits of atypical antipsychotics and possible treatment alternatives, as well as if *no pharmacologic treatment* is warranted."[14] As part of a non-pharmacologic treatment plan, the researchers noted that "[p]sychosocial treatments should be used whenever appropriate."[15] Other recent studies have replicated these findings that antipsychotics have questionable efficacy.[16]

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[13] Jin, Shih, Golshan, *et al.*, *Comparison of Longer-Term Safety and Effectiveness of 4 Atypical Antipsychotics in Patients Over Age 40: A Trial Using Equipoise-Stratified Randomization*, 74(1) J. Clin. Psychiatry 10, 13, 16 (Jan. 2013).

[14] *Id.* at 16–17 (emphasis added).

[15] *Id.*at 17.

[16] *See, e.g.*, Wunderink, Lex, Nieboer, *et. al.*, *Recovery in Remitted First-Episode Psychosis at 7 Year of Follow-up of an Early Dose Reduction/Discontinuation or*

Further concerns about the degree of efficacy of these second-generation drugs comes from the results of one of the most comprehensive studies of the efficacy of antipsychotics on the treatment of schizophrenia.[17] This study, known as the Clinical Antipsychotic Trial of Intervention Effectiveness ("CATIE"), was initiated by the National Institute of Mental Health to compare the effectiveness of antipsychotic drugs, and the study protocols were made available for public comment.[18] After approving the protocol, the study tested the effectiveness of second-generation antipsychotic drugs over the course of four years on 1,493 patients diagnosed with chronic schizophrenia between 18 and 65 years of age, and was conducted at 57 clinical sites across the United States.[19] Only a minority of patients, regardless of the drug administered, were able to continue treatment past the 18-month phase.[20] In summary, the researchers concluded that "patients with chronic schizophrenia in this study discontinued their antipsychotic study medications at a high rate, indicating substantial limitations in the effectiveness of the

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Maintenance Strategy, 70(9) JAMA Psychiatry 913–920 (2013) (suggesting that long-term treatment with antipsychotics is not necessary or effective for some individuals); Martin Harrow & Thomas H. Jobe, *Does Long-Term Treatment of Schizophrenia with Antipsychotic Medications Facilitate Recovery?*, Schizophrenia Bulletin (2013), *available at* http://schizophreniabulletin.oxfordjournals.org/content/39/5/962.full (noting that longitudinal studies "clearly indicate that not all schizophrenia patients need continuous antipsychotics for a prolonged period"); Martin Harrow & Thomas H. Jobe, *Factors Involved in Outcome and Recovery in Schizophrenia Patients Not on Antipsychotic Medications: a 15-year Multifollow-Up Study*, 195(5) J. Nervous & Mental Disease 406, 406, 408–13 (2007) (showing, in a 15-year multi-follow-up study, that a larger percentage of schizophrenia patients not on antipsychotics showed periods of recovery and better global functioning than schizophrenia patients who took antipsychotics).

[17] *See* Lieberman, Stoup, McEvoy, *et. al.*, *Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia*, 353 New England J. Medicine 1209 (2005).

[18] *Id.* at 1210.

[19] *Id.* at 1209–10.

[20] *Id.* at 1215.

drugs."[21] The researchers also made observations about the serious side effects of these drugs that, combined with their lack of efficacy, led to such a high discontinuance rate.[22]

In sum, research indicates that real questions exist regarding the efficacy of antipsychotic drugs to treat schizophrenia. 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.

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

Even second-generation antipsychotics (such as olanzapine) may cause the development of very serious side effects, the most significant of which involve extrapyramidal side effects and metabolic changes. This is especially troubling in light of the fact that the side effect profile of second-generation antipsychotics was, until recently, commonly thought to reduce incidence of extrapyramidal side effects in exchange for increased risk of metabolic 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."[23] These symptoms of tardive dyskinesia may remain long after the patient has discontinued the use of antipsychotics. The involuntary

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[21] *Id.* at 1218.

[22] *Id.* at 1215, 1218.

[23] 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).

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.[24]

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.[25] "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."[26] 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.[27] 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.[28]

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.[29] Parkinsonism can also cause drooling, cogwheel rigidity, loss of spontaneous and associated movements, blank stare, dulled facial

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[24] 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).

[25] 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).

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

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

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

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

expressions, and stooped posture.[30] Although these symptoms are usually reversible, they can be extremely unpleasant and occur in about 15 percent of patients receiving conventional antipsychotic drugs.[31]

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.[32] 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,[33] with some estimates placing it as high as 30 percent.[34]

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.[35] There is also evidence that the risk of sudden death is more than two times greater for patients receiving conventional antipsychotic drugs than for nonusers.[36]

A new class of antipsychotic drugs was developed in the early 1990s. This class, referred to as atypical antipsychotics, appeared in early studies to cause a lower incidence

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

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

[32] *Id.*

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

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

[35] *Id.* at 438.

[36] 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).

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.[37] Significantly, the comprehensive CATIE study cited above noted that, despite the use of a first-generation antipsychotic and three atypical antipsychotics in the study, "there were no significant differences among the groups in the incidence of extrapyramidal side effects, akathisia, or movement disorders as reflected by rating-scale measures of severity."[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

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[37] U.S. Food & Drug Admin., *Zyprexa Medication Guide* (2009), *available at* www.fda.gov/downloads/drugs/drugsafety/ucm134700.pdf; U.S. Food & Drug Admin., *Label for Risperidal* (2009), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020272s056,020588s044,021346s033,021444s03lbl.pdf; U.S. Food & Drug Admin., *Highlights of Prescribing Information: Quetiapine Tablets (marketed as Seroquel)* (2009), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020639s045s046lbl. pdf. *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].").

[38] Lieberman, Stoup, McEvoy, *et. al.*, *supra*, at 1212. This finding is especially significant because the first-generation drug used in the CATIE study was selected because it generally had the lowest incidence of extrapyramidal side effects among first-generation antipsychotics. *Id.*

[39] Jenna Griffiths & Pascale Springuel, *Atypical Antipsychotics and Impaired Glucose Metabolism*, 15 World Health Org. Drug Info. 152, 152–54 (2001), *available at* http://apps.who.int/medicinedocs/en/d/Jh2989e/. *See also* Anon., Medical News Today, *Metabolic Side Effects Such as Obesity and Diabetes Caused by Antipsychotic Medications* (2012), *available at* http://www.medicalnewstoday.com/releases/241084.php (noting that the researchers believe that atypical antipsychotic drugs trigger a specific metabolic protein that interferes with proper cellular growth, inflammation, and insulin signaling, thereby causing obesity and diabetes).

concerns that should not be taken 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 9% 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 patients with dementia.[44] The CATIE study also noted that olanzapine had effects consistent with potential development of metabolic syndrome and was associated with greater increases in glycosylated hemoglobin, total cholesterol, and

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[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 apnea, 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(8) 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).

[44] U.S. Food & Drug Admin. Public Health Advisory, *Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances* (2005), *available at* http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm053171.

triglycerides, even with adjustment for the duration of treatment.[45] Further, patients in the CATIE study gained an average of 2 pounds per month on the drug, with 30% of patients gaining 7% or more of their baseline bodyweight.[46] Thus, although the prevalence of extrapyramidal side effects from atypical antipsychotics is a matter of debate, they have generated a new set of problematic metabolic side 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 rate, seizures, differences in body temperature, constipation, nausea, vision changes, liver problems, sleepiness, restlessness, low blood pressure, and dry mouth.[47] 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.[48]

Lorazepam, another drug prescribed for Mr. Allmond, is not an antipsychotic but can be prescribed to alleviate the side effects of antipsychotic drugs.[49] Lorazepam is a high-potency benzodiazepine, a class of drugs used to treat anxiety, insomnia, and convulsions.[50] Common side effects of benzodiazepine use include cognitive impairment and anterograde amnesia.[51] Further, discontinuance of benzodiazepines often results in

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[45]Lieberman, Stoup, McEvoy, *et. al.*, *supra*, at 1215. *See also* Jin, Shih, Golshan, *et. al.*, *supra* at 15 (noting that the one-year incidence of metabolic syndrome for patients taking atypical antipsychotics was 36.5%)

[46] Lieberman, Stoup, McEvoy, *et. al.*, *supra*, at 1215.

[47] See the U.S. Food and Drug Administration Patient Information Sheets cited in note 37 *supra.*

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

[49] The ALJ record does not make clear whether lorazepam was administered by the Perkins staff as a primary treatment for Mr. Allmond's schizophrenia or as a potential ameliorative agent for the side effects of the antipsychotics.

[50] Guy Chouinard, *Issues in the clinical use of benzodiazepines: potency, withdrawal, and rebound*, 65 (Supp. 5) J. Clin. Psychiatry 7 (2004).

[51] *Id.* at 9.

rebound anxiety—a condition where the symptoms the benzodiazepine was used to control return with greater intensity after discontinuation of treatment.[52] The strength of discontinuance effects increases with the duration and dosage of benzodiazepine treatment, though discontinuation symptoms as extreme as seizures can occur after less than 15 days of use at therapeutic dosage.[53]

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 v. Wilzack*, 319 Md. 485, 503, 573 A.2d 809, 817 n.6 (citing *Washington*); *Myers v. Alaska Psychiatric Institute*, 138 P.3d 238, 241 (Alaska 2006) ("[P]sychotropic drugs* * * are 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 conflicting data regarding the efficacy and side effect profiles of antipsychotic drugs in the treatment of schizophrenia specifically. 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.

Researchers 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 and the ensuing negotiation can be therapeutically valuable, and that

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[52] *Id.* at 7–12. Benzodiazepine addiction commonly occurs in patients attempting to avoid the unpleasant rebound effects of these drugs. *Id.* at 11.

[53] Hu X, *Benzodiazepine withdrawal seizures and management*, 104(2) J. Okla. St. Med. Assoc. 62, 62–64 (2011).

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.[54] As noted above, researchers have concluded that psychosocial treatments should be used whenever appropriate.[55] In particular, one study has shown cognitive behavior therapy should be used in the treatment of schizophrenia, as there appears to be a clinically significant benefit to such treatment.[56] Even when antipsychotic drugs are employed, "skillful negotiat[ion]" is required for effective treatment because the symptomatic denial of problems, coupled with the adverse effects of drugs, undermine compliance.[57] "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 delusional disorder admit that forcibly medicating a patient can jeopardize an already perilous therapeutic relationship and undermine long-term treatment.[58]

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

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[54] 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).

[55] Jin, Shih, Golshan, *et al.*, *supra*, 74(1) J. Clin. Psychiatry 74(1) 10–18 (Jan. 2013).

[56] *See generally* D. Turkington *et. al.*, *Cognitive Behavior Therapy for Schizophrenia*, 163(3) Am. J. Psychiatry 365 (2006).

[57] Theo C. Manschreck, *Delusional Disorder: The Recognition and Management of Paranoia*, 57 J. Clinical Psychiatry 32, 37 (1996). Though Mr. Allmond does not suffer from delusional disorder, as noted in the discussion above, the importance of establishing doctor/patient rapport applies similarly to schizophrenia.

[58] 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, 363 (2006).

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."[59]

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. "Patient involvement in decisions about medication * * * is critically important to compliance."[60]

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."[61] 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.[62] Moreover, even patients who had refused and later consented to treatment fared better outside the hospital than those who never refused.[63] The researchers suggested that "a healthy skepticism about doctors,

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

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

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

[62] *Id.* at 72.

[63] *Id.*

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.[64]

Thus, these findings show that the supposed "substantial risk of indefinite continued hospitalization" without forced medication asserted by the ALJ is not consistent with recent scientific research; in fact, refusals may lead to better long-term treatment outcomes.

Accordingly, striking down Section 10-708(g) to the extent that it permits forced medication of competent individuals who do not pose a danger to themselves or others in the institution will not compromise their treatment or undermine state interests in treating such individuals. 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

Concerns about the limited effectiveness of antipsychotic medications are legitimate, and potentially devastating 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, a finding that Section 10-708 as amended violates the Maryland Declaration of Rights insofar as it as permits forcible treatment with antipsychotic medications of individuals who pose a danger neither to themselves or others in the institution will not result in disastrous consequences for such involuntarily-committed patients or for the State and may in fact improve treatment prospects.

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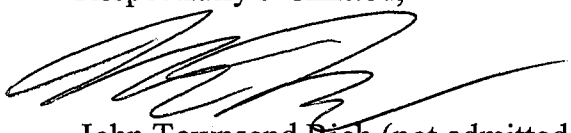
[64] *Id.*

Respectfully submitted,



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September 29, 2015

STATEMENT OF TYPE STYLE AND POINT SIZE

This brief uses 13-point Times New Roman font.

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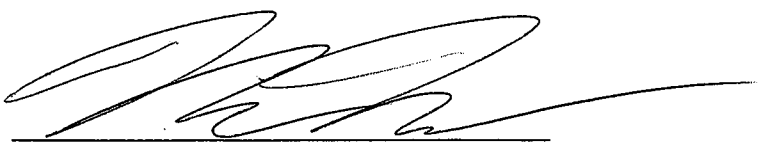

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