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## REGULATING RESEARCH WITH VULNERABLE POPULATIONS: LITIGATION GONE AWRY

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### I. INTRODUCTION

Current litigation in New York, *T.D. v. New York State Office of Mental Health* (OMH),<sup>1</sup> challenges OMH regulations governing research with human subjects. The outcome of this litigation will ultimately determine whether research in New York may be conducted with children and with incapacitated adults, and under what circumstances. The repercussions may prevent numerous studies from going forward and ultimately put a halt to research that may have provided participants with access to effective treatment and significantly improved the well-being of other individuals suffering from mental illness and other cognitive impairments.

The New York experience demonstrates the consequences of litigation in which the central issues of a complex matter are inadequately examined. The result in this instance may be the establishment of research rules which will have significant adverse impacts on individuals with mental illness or other cognitive impairments, their family members, and researchers in this and other fields. The New York experience stands in stark contrast to the consensus

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1. 650 N.Y.S.2d 173 (N.Y. App. Div. 1996), *appeal dismissed* by 680 N.E.2d 617 (N.Y. 1997), *leave to appeal granted* by 684 N.E.2d 281 (N.Y. 1997), and *appeal dismissed* by 1997 WL 785461 (N.Y. Dec. 22, 1997) (The final decision in this case post-dated the preparation of this article.).

building approach adopted by Maryland,<sup>2</sup> both in its process and likely outcome.

## II. BACKGROUND

### A. *History of Research in Office of Mental Health Facilities*

OMH has included research into the causes of severe and persistent mental illness as one component of its mission for more than 100 years. In 1890, legislation was passed in New York State placing all chronically mentally ill individuals under the protection and care of the state.<sup>3</sup> Several years later, additional legislation was passed creating the nation's first institute dedicated to psychiatric research. The New York State Psychiatric Institute (NYPI) opened in 1896 and has been continuously supported by the state until the present time. NYPI was mandated to conduct research into the causes, prevention, and treatment of mental illness.<sup>4</sup> A second dedicated research facility, the Nathan Kline Institute for Psychiatric Research, was opened by OMH in 1952. Research studies are also conducted at many of the clinical psychiatric hospitals operated by the state. As recognized by the National Institute of Mental Health, "[t]he State of New York includes some of the most distinguished research institutions in the United States."<sup>5</sup> Research carried out within OMH facilities is under the overall supervision of a Deputy Commissioner for Research. All research is carried out subject to the approval of, and ongoing review and monitoring of, a federally-approved institutional review board (IRB).<sup>6</sup> Among the milestones accomplished by researchers in OMH were the discovery of the infectious etiology of "general paresis of the insane," the first genetic studies of schizophrenia, the first clinical trials of chlorpromazine (the first antipsychotic medication to become available in the United States), the first lithium clinic in the country (for treatment of manic depressive illness), and, more recently, the discovery of the genetic defect in Wilson's disease (a disease of copper metabolism that can cause a type of psychosis).

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2. See Jack Schwartz, Office of Md. Att'y Gen., Third Report of the Attorney General's Research Working Group (August 1997) (the Third Report is reprinted in Appendix B to this issue of the *Journal of Health Care Law & Policy*).

3. See Act of April 15, 1890, ch. 126, 1890 N.Y. Laws 303.

4. See LAWRENCE C. KOLB & LEON ROIZIN, *THE FIRST PSYCHIATRIC INSTITUTE* 7-8 (1993).

5. Letter from Rex William Cowdry, Acting Director, National Institute of Mental Health, to Mr. John V. Tauriello, Deputy Commissioner of Mental Health and Counsel, New York State Office of Mental Health (January 26, 1996).

6. See Protection of Human Subjects, 45 C.F.R. § 46.101 (1997).

*B. Research Regulations Prior to 1990*

In 1975, the New York State Department of Mental Hygiene, of which what is now OMH is one component agency, issued regulations for research involving human subjects.<sup>7</sup> These brief regulations provided the following:

- Research participation could not come into substantial conflict with the patient's individual service plan or deprive a patient of any right or privilege.<sup>8</sup>
- Informed written consent was required to be obtained from patients.<sup>9</sup> If a patient did not have sufficient capacity, consent could be obtained from the facility director if the IRB established that the project had overriding therapeutic importance for a condition presented by the patient and that the project could not be carried out without the participation of such patients.<sup>10</sup>
- Use of experimental drugs or treatment procedures had to be approved by the OMH Division of Research.<sup>11</sup>

In the late 1980s, under the leadership of the Deputy Commissioner for Research, the adequacy of these research regulations was reviewed.<sup>12</sup> Particular attention was given to the need to safeguard the most vulnerable populations participating in research.<sup>13</sup> At this time, a number of significant problems were identified.<sup>14</sup> As an interim measure, while revised regulations were being developed, OMH issued a policy memorandum<sup>15</sup> which addressed some of the most critical deficiencies by adding the following requirements:

- Researchers were required to obtain an assessment of capacity of all adult patients, both outpatients and inpatients, and document the results in the individual's medical record.<sup>16</sup> For outpatient protocols which involved no more than minimal risk and/or a non-vulnerable subject population, the IRB was authorized to permit

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7. See N.Y. COMP. CODES R. & REGS. tit. 14, § 27.10 (1997).

8. See *id.* § 27.10(a).

9. See *id.* § 27.10(b).

10. See *id.*

11. See *id.* § 27.10(c).

12. See Memorandum from Heinz Lehmann, Deputy Commissioner for Research, New York State Office of Mental Health and Susan J. Delano, Clinical Research Coordinator, Research Foundation for Mental Hygiene, Inc. to OMH Facility Directors and IRB Chairpersons (July 31, 1987) (unpublished memorandum, on file with authors).

13. See *id.*

14. See *id.*

15. See *id.*

16. See *id.*

the research team itself to make the capacity assessment.<sup>17</sup> All other outpatient protocols were subject to the capacity assessment procedures for inpatient protocols.<sup>18</sup> These procedures required that the capacity of inpatients be assessed by at least two people, including an investigator from the research team and a member of the treatment team who was not affiliated with the research.<sup>19</sup> Both were required to be licensed health care professionals, and one was required to be a psychiatrist or clinical psychologist.<sup>20</sup>

- For patients found capable of consenting, and with the patient's consent, family members, significant others, and close friends who had been involved in treatment decisions were to be informed about the patient's decision to participate.<sup>21</sup>
- Consent for an incapable patient's participation in research was required to be obtained from both the facility director *and* the patient's spouse, parent, adult child, guardian, or court of competent jurisdiction.<sup>22</sup> Documentation of the patient's lack of objection to participation was required.<sup>23</sup>
- The researcher was required to honor the incapacitated patient's objection to participation unless a court order was obtained.<sup>24</sup> It was assumed that a court would only authorize research offering therapy not available outside the research context where there was no acceptable alternative treatment and the research was consistent with the treatment needs of the patient.<sup>25</sup>

### C. *Development of 1990 Regulations*

As noted above, the 1975 regulations were inadequate, particularly with regard to issues of capacity and surrogate consent.<sup>26</sup> Building on the interim guidelines, OMH undertook a revision of its research regulations. Three major goals guided this process:

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17. *See id.*

18. *See id.*

19. *See id.*

20. *See id.*

21. *See id.* at 2.

22. *See id.* at 3.

23. *See id.*

24. *See id.* at 4.

25. *See id.*

26. *See* N.Y. COMP. CODES R. & RECS. tit. 14 § 27.10 (1997).

- 1) maximization of patient autonomy and control by patients over their participation in research;
- 2) protection of the rights and welfare of these potentially vulnerable populations; and
- 3) creation of an environment that makes it possible to carry out important and needed research with these patient groups.<sup>27</sup>

In drafting the regulations, OMH attempted to achieve a principled and workable balance of these goals. Based upon clinical reality, respect for patients and developments in the law, a consensus had developed among health professionals that psychiatric patients should be presumed capable of consenting to research participation.<sup>28</sup> Moreover, status as an inpatient or outpatient was not to be considered determinative of capacity.<sup>29</sup> However, since some patients do lack capacity to consent, IRBs were charged with the responsibility of examining the proposed research and the subject population to tailor capacity assessment procedures to the specific research protocol.<sup>30</sup> When an IRB had reason to believe that patients might lack sufficient capacity to give informed consent, the IRB was authorized to require that capacity assessments be conducted by someone not affiliated with the research and to set specific qualifications for the person(s) who assessed capacity.<sup>31</sup>

The regulations also provided that a member of the participant's treatment team was required to approve all research that involved more than minimal risk.<sup>32</sup> The care and treatment of hospitalized patients is under the direction of a multi-disciplinary treatment team, usually consisting of a psychiatrist, social worker, nurse, activities therapist, and often a psychologist.<sup>33</sup> This treatment arrangement is standard for all inpatients, including those participating in research protocols.

In addition, the regulations stated that all patients, regardless of capacity, could, at any time prior to or during participation in re-

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27. See Susan J. Delano & Jay L. Zucker, *Protecting Mental Health Research Subjects Without Prohibiting Progress*, 45 HOSP. & COMMUNITY PSYCHIATRY 601-03 (1994).

28. See *Rivers v. Katz*, 495 N.E.2d 337, 342-43 (N.Y. 1986).

29. See N.Y. COMP. CODES R. & REGS. tit. 14 § 527.10.

30. See *id.* § 527.10(e)(2)(ii).

31. See *id.*

32. See *id.* § 527.10(d)(3). "Minimal risk" is defined to mean that "the risks of harm anticipated in the proposed research are not greater . . . than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." § 527.10(d)(5) .

33. See Paul Rodenhauer, *Psychiatrists as Treatment Team Leaders: Pitfalls and Rewards*, 67 PSYCHIATRIC Q. 11 (1996).

search, object and be withdrawn from participation.<sup>34</sup> For incapable participants, the objection of any of the members of the classes of authorized surrogates was equally effective.<sup>35</sup> Any such objection was determinative except that, if the research provided a prospect of direct benefit available only in the context of the research, participation in such research could occur if approved by a court.<sup>36</sup> Moreover, the IRB was required to determine, for research involving incapable subjects, that the research could not be done without such subject's inclusion and that the research was likely to produce knowledge of overriding therapeutic importance for a condition presented by the patients in question.<sup>37</sup>

Finally, preference was to be given to surrogates chosen by the patient.<sup>38</sup> In the absence of a patient-chosen surrogate, consent could be obtained from a patient's spouse, parent, adult child, adult sibling, or guardian.<sup>39</sup> If no surrogates in the other categories were available, consent could be obtained from a court or, in special cases, (e.g., persons in non-traditional relationships) consent could be provided by a carefully defined "close friend."<sup>40</sup> This identification of potential surrogate decision-makers reflected the provisions found in the New York state statute enacted in 1987 concerning "Do Not Resuscitate" orders.<sup>41</sup>

Two additional factors regarding the OMH regulations are relevant to this discussion. The first is that the OMH regulations supplemented the federal regulations which govern how human subjects research is conducted in this country.<sup>42</sup> The OMH regulations did not establish or change any principles or categories with regard to likelihood of therapeutic benefit of the proposed research, degrees of risk or funding source.

The second factor was that the process of developing the regulations included extensive consultation with patient advocates, clinicians, researchers, state agency personnel - particularly the Department of Health and members of IRBs. Thereafter, as required

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34. See § 527.10(e)(2)(vi), (vii).

35. See § 527.10(e)(2)(viii).

36. See § 527.10(e)(2)(vi-viii).

37. See § 527.10(d)(6).

38. See § 527.10(e)(2)(iii), (iv).

39. See § 527.10(e)(2)(iv).

40. *Id.*

41. N.Y. PUB. HEALTH LAW §§ 2960-72 (McKinney, 1997).

42. See Protection of Human Subjects, 45 C.F.R. § 46 (1997) (now referred to as the Common Rule); Protection of Human Subjects, 21 C.F.R. § 50 (1997); Institutional Review Boards, 21 C.F.R. § 56 (1997).

by state law,<sup>43</sup> draft regulations were published in the State Register for comment.<sup>44</sup> The proposed regulations were also distributed to state agencies, facilities licensed and operated by the OMH, local government units, the Mental Health Services Council (an advisory group, to the OMH Commissioner), consumer groups, and advocacy groups. A number of groups provided comments.<sup>45</sup> These comments questioned many aspects of the proposed regulations, including their applicability, definitions, and issues related to surrogate consent. Following are summaries of the comments that are relevant to the issues raised in the litigation:<sup>46</sup>

- Six comments stated that research involving incapable subjects should only be permitted when it involves a benefit to the subject. OMH responded that while benefit to an individual patient is highly desirable, research into many currently irreversible conditions such as Huntington's Disease and Alzheimer's Disease cannot benefit the subjects of the research.<sup>47</sup> To prohibit research when there is no direct benefit to the patient would mean the end to research into many serious illnesses. To clarify that the IRB is required to conduct a risk/benefit analysis, the proposed regulations were revised to give greater emphasis to the sections of the federal regulations relating to evaluation of risks and benefits, and the minimization of risks.<sup>48</sup>
- One comment suggested that when a person's capacity is questionable and the research involves more than minimal risk, an independent qualified consultant should determine capacity.<sup>49</sup> OMH responded that the proposed regulations required the IRB to evaluate the nature of the research and the subject population to determine when

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43. See N.Y. A.P.A. Law §§ 201-02 (McKinney, 1997).

44. See *Mental Illness Research*, N.Y. St. Reg., May 23, 1990, at 23-24 (codified at N.Y. COMP. CODES R. & RECS. tit. 14, § 527.10 (1997)).

45. Twenty one comments were timely received. These were submitted by mental health professionals and providers such as state and county Mental Health Associations, and operators of licensed psychiatric inpatient units; by advocacy groups such as Project Release, Mental Health Recipient Empowerment Project, and the Commission on Quality of Care for the Mentally Disabled; and by individuals. In addition, a submission by Disability Advocates, Inc. which was received subsequent to the time period for comments established by the New York State Administrative Procedure Act was also considered.

46. See *generally* *Mental Illness Research*, N.Y. St. Reg. August 29, 1990, at 27-31 (1997) [hereinafter *Mental Illness Research*].

47. See *id.* at 30.

48. See *id.*; see also *Protection of Human Subjects*, 45 C.F.R. § 46.111 (1997).

49. See *Mental Illness Research*, *supra* note 46, at 30.



an independent assessment of capacity is required.<sup>50</sup> This complex decision is best left to the judgment of the IRB.

- Two comments stated that the decision in *Rivers v. Katz*<sup>51</sup> requires that capacity assessments/determinations must be made by a court.<sup>52</sup> This is not OMH's interpretation of the *Rivers* opinion.<sup>53</sup> Such a requirement would mean that all patients would be presumed incapable of consenting until a judicial determination of capacity is made.<sup>54</sup> This stigmatizing practice would be detrimental to OMH's ability to provide treatment and would impose a tremendous and unwarranted barrier to the conduct of research.<sup>55</sup>
- Two comments stated that it should be conclusively assumed that all patients have sufficient capacity to consent.<sup>56</sup> OMH disagreed believing that some patients would lack capacity, and thus, safeguards are required to ensure that the interests of those patients who lack capacity are protected.<sup>57</sup> The IRB must determine who shall assess capacity, and the person obtaining consent must sign the consent form to attest to the person's capacity.<sup>58</sup>
- Eleven comments challenged surrogate consent.<sup>59</sup> OMH responded that the surrogates named in the regulations, particularly those chosen by the patient, can more appropriately articulate the patients' wishes and interests than can judges.<sup>60</sup>
- Four additional comments challenged the authority of a "close friend" to consent on behalf of an incapable subject.<sup>61</sup> OMH responded that "close friend" was incorporated in recognition of the large number of people in non-traditional relationships and the large number of people whose primary care giver is not a family mem-

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50. *See id.*

51. 495 N.E.2d 337 (N.Y. 1986).

52. *See* Mental Illness Research, *supra* note 46, at 30.

53. *See id.*

54. *See id.*

55. *See id.*

56. *See id.*

57. *See id.*

58. *See id.*

59. *See id.* at 30-31.

60. *See id.* at 31.

61. *Id.*

ber.<sup>62</sup> As noted above, this principle had already been recognized in New York law.<sup>63</sup>

- Nine comments asked for specification of the conditions under which an application could be made for a court order to override a patient's objection.<sup>64</sup> This suggestion was adopted.
- One comment objected to any provision allowing an incapable subject's objection to be overridden.<sup>65</sup> OMH responded that the override provision is intended for situations in which there is no standard treatment for a condition or the patient is refractory or intolerant of standard therapy.<sup>66</sup> This would allow treatment over objection with an experimental drug, but only when specifically authorized by a court.

Based upon the public comment, the proposed regulations were revised. The revised proposed regulations were distributed, the seven responses received, again presenting divergent perspectives, and all responses were considered prior to final adoption.<sup>67</sup>

#### D. *Experience with 1990 Regulations*

It appears that researchers and IRBs made the transition from the minimal 1975 regulations to the 1990 regulations in a workable manner. The regulations were in effect for approximately five years, and other than the litigation, we are aware of no complaints about the regulations or their implementation. It should be noted that many avenues for complaints were available including the Commission on Quality of Care for the Mentally Disabled, an independent state oversight body. Moreover, as required by the federal research regulations,<sup>68</sup> all research consent forms include the name and telephone number of a person that participants (or surrogates) may contact if they have any questions about their rights.<sup>69</sup> Typically this person is the IRB chairperson. In addition, individuals and organizations routinely contact the Commissioner of OMH with questions and concerns, but no complaints regarding the research regulations were

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62. *See id.*

63. N.Y. PUB. HEALTH LAW §§ 2960-72 (McKinney, 1997).

64. *See* Mental Illness Research, *supra* note 46, at 30.

65. *See id.*

66. *See id.*

67. These comments were submitted by Disability Advocates, Inc., New York Lawyers for the Public Interest, Inc., the Free Association for Rights and Representation, Inc., two individuals and two representatives of research institutions.

68. *See* Protection of Human Subjects, 45 C.F.R. § 46.116(7) (1997).

69. *See id.*

received to our knowledge. Finally, the regulations were described in a widely read peer-reviewed publication,<sup>70</sup> and the Federal Office for Protection from Research Risks has noted its appreciation of "the commitment of the New York State Department of Mental Health to the protection of human subjects."<sup>71</sup>

### III. SETTING RESEARCH POLICY THROUGH LITIGATION

#### A. *Summary of Plaintiff's Claims*

While the 1990 regulations were considerably more protective of research participants than the previous regulations, they were substantially flawed in the opinions of some groups. In 1991, three legal advocacy groups - Disability Advocates, New York Lawyers for the Public Interest, and The Mental Hygiene Legal Service, on behalf of six patients hospitalized at various New York State Psychiatric Centers brought the *T.D.* case against OMH and the State Department of Health.<sup>72</sup> None of the six patients claimed to have been a participant in a research project. However, they alleged that they were "fearful" of being included in research against their will.<sup>73</sup> These patients had received standard medications administered over their objections,<sup>74</sup> in accordance with a 1986 ruling of New York's highest court permitting such treatment upon a judicial determination that the patient was incapable of making treatment decisions and that the proposed treatment was appropriate.<sup>75</sup>

The *T.D.* suit concerned both OMH operated facilities as well as OMH licensed facilities (*i.e.*, psychiatric units in general hospitals and in teaching hospitals affiliated with academic departments of psychiatry) in New York and was limited to more than minimal risk research with minors and with adults who lack capacity to consent.<sup>76</sup> The plaintiffs asserted a legal claim with two main elements:

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70. See generally Delano & Zucker, *supra* note 27.

71. Letter from J. Thomas Puglisi, Director, Division of Human Subject Protections, National Institutes of Health, to Susan Delano, Clinical Research Coordinator, Research Foundation for Mental Hygiene, Inc. (December 2, 1996) (unpublished letter on file with authors).

72. *T.D. v. New York State Office of Mental Health*, 626 N.Y.S.2d 1015 (N.Y. Sup. Ct. 1995), *aff'd* 650 N.Y.S.2d 173 (App. Div. 1996), *appeal dismissed by* 680 N.E.2d 617 (N.Y. 1997), *leave to appeal granted by* 684 N.E.2d 281 (N.Y. 1997), *and appeal dismissed by* 1997 WL 785461 (N.Y. Dec. 22, 1997).

73. *T.D.*, 650 N.Y.S.2d at 177.

74. See *id.*

75. See *Rivers v. Katz*, 495 N.E.2d 337, 343 (1986).

76. *T.D.*, 626 N.Y.S.2d at 1017.

1) that OMH lacked the authority to promulgate regulations regarding research on human subjects because state law granted such authority to the Department of Health;<sup>77</sup> and

2) that the specific regulations governing the procedures for the "non-consensual participation by mental patients in potentially high risk [non-therapeutic] experiments"<sup>78</sup> violated constitutional rights to privacy and due process by permitting, inter alia, research consent from a relative or "close friend" without a judicial determination of incapacity and formal designation of a surrogate.<sup>79</sup>

The parties filed cross motions for summary judgment on these legal claims in 1992.<sup>80</sup> Plaintiffs alleged that risk and harm were associated with research participation, but as the motions addressed only questions of law, these allegations were never proven nor rebutted.<sup>81</sup> Moreover, neither the actual risks and benefits of research participation nor the concepts and mandates of the federal regulations and state law governing the conduct of research was ever meaningfully explored in this litigation.

In 1995, the court granted the Plaintiffs' Motion for Summary Judgment, stating clearly that it was not ruling on the constitutional claims but only on the question of OMH's statutory authority to issue regulations concerning research.<sup>82</sup> The court further limited the scope of its ruling to non-federally funded research studies.<sup>83</sup>

Defendants appealed the trial court's statutory ruling, and the plaintiffs appealed that court's failure to rule on the constitutional issues.<sup>84</sup> In 1996, the intermediate appeals court, the First Appellate Department of the New York State Supreme Court, issued its decision on the cross appeals of the trial court's ruling on the cross motions for summary judgment.<sup>85</sup> The appellate court concurred with the lower

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77. *See id.* at 1021.

78. *Id.* at 1017.

79. *See id.*

80. *See id.* at 1018.

81. Plaintiff's motion for summary judgment was supported by affidavits which claimed research participants were exposed to extreme risk and suffered terrible harms. In support of these claims, plaintiffs attached over 2,500 pages of excerpts from investigative reports, consent forms, the Physicians Desk Reference, etc. Defendants contended that, when read in their entirety, the reports, forms and PDR demonstrated the inaccuracy of the conclusions drawn by the plaintiffs.

82. *See T.D.*, 626 N.Y.S.2d at 1022-23.

83. *See id.* at 1023-24.

84. *See T.D.*, 650 N.Y.S.2d 173.

85. *See id.*

court that OMH lacked the statutory authority to issue the regulations, and also ruled on the constitutional questions.<sup>86</sup>

Many aspects of the court's constitutional analysis and conclusions are confusing, but the essence of the ruling was that the OMH regulations violated the right to due process in that they did not specify uniform qualifications and protocols for the independent evaluation of research participants' mental capacity, did not provide for notice of that evaluation to the person or a means to object to the determination, permitted a relative to give surrogate consent without a judicial proceeding, and thus permitted non-therapeutic research which posed "more than minimal risk" to research subjects without their consent or the consent of a suitable surrogate.<sup>87</sup> Like the lower court, the decision clearly states that it applies only to non-federally funded and non-therapeutic research.<sup>88</sup> The court held that individuals who lack decision-making capacity may *not* participate in such research if that research poses more than minimum risk to the research subject unless the research subject has previously given valid "specific consent" or a suitable surrogate chosen by the subject has given consent.<sup>89</sup> Although the plaintiffs obtained two court decisions invalidating the regulations, they returned to the appellate division requesting that it clarify its decision and broaden the scope to apply to federally-funded studies and to therapeutic studies with the populations in question.<sup>90</sup> OMH also asked the court to clarify its decision, but both motions were denied.<sup>91</sup>

Plaintiffs then appealed to New York's Court of Appeals, the state's highest tribunal, again seeking to broaden the scope of the ruling to apply to federally-funded and to therapeutic research involving incapable adults and minors.<sup>92</sup>

### *B. Reallocating Agency Jurisdiction*

The plaintiffs have contended, and the courts have thus far agreed, that the New York State Department of Health (DOH) has sole legal authority to issue regulations concerning human subject research.<sup>93</sup> It is true that DOH has authority in this area under New

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86. *See id.* at 184-94.

87. *Id.*

88. *See id.* at 184, 192.

89. *Id.* at 177.

90. *See* Plaintiffs'-Appellants' Notice of Motion for Leave to Appeal at 23-35, 650 N.Y.S.2d 173.

91. *See T.D.*, 650 N.Y.S.2d at 176.

92. *See id.* (at the time of the original writing of this article, the appeal was pending).

93. *See id.*

York State Public Health Law,<sup>94</sup> yet the court ignored important facts. It had been a longstanding understanding between DOH and OMH that OMH had the authority to issue regulations which provided specific requirements for psychiatric research. In fact, DOH had not promulgated regulations regarding human subjects research, but had participated in the development of, and had recognized, the OMH regulations and system for monitoring psychiatric research. This reliance upon OMH expertise in exercising administrative responsibility continues, for example, with OMH licensing the psychiatric units in general hospitals whose overall licensure is statutorily committed to DOH. Thus the court's invalidation of the OMH regulations upset interagency coordination that had worked well for years, and did so for reasons having nothing to do with the substance of the research regulations.

### C. *Misperception of Risks and Benefits*

As noted above, none of the plaintiffs in the law suit had suffered any tangible harms as a result of participation in research, since, in fact, none of them had participated in research. Rather, the suit was based on their fears that they might be included in a research protocol without their informed consent.<sup>95</sup> Because there was no real harm suffered, the claims were based upon hypothetical harms. Unlike cases where actual injury is suffered and the lawyers for the plaintiffs must litigate based upon evidence of harm, in this case the lawyers were free to assert possible harms untethered to facts. The structure of the litigation thus lent itself to rhetoric. Moreover, because the trial court ruled on motions for summary judgment and no real factual record was developed, the appellate review of the issues reflected the emotions associated with risk and vulnerability rather than the reality of research.

The plaintiffs contended that high-risk research was being carried out with minors and incapable adults, and that this high-risk research offered absolutely no benefit to the participants<sup>96</sup> and was akin to Nazi atrocities.<sup>97</sup> In the papers filed with the court of appeals, plaintiffs

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94. See N.Y. PUB. HEALTH LAW § 2446 (McKinney, 1997).

95. See *T.D.* 626 N.Y.S.2d 1015.

96. See Plaintiffs' Complaint at para. 21, 28, *T.D. v. New York State Office of Mental Health*, 626 N.Y.S.2d 1015 (N.Y. Sup. Ct. 1995) (No. 5136/91); Plaintiffs'-Appellants' Statement in Support of Motion for Leave to Appeal at 4, *T.D. v. New York State Office of Mental Health and New York Department of Health*, 650 N.Y.S.2d 173 (App Div. 1996) (No. 5136/91) [hereinafter Plaintiffs'-Appellants' Motion for Leave to Appeal].

97. See Patricia Cohen, *Patients at Risk: Experiments in Mental Hospitals*, NEW YORK NEWS-DAY, Feb. 3, 1993, at 3. "We may not have the horror stories in numbers, but the possibility

made the following statement: "This appeal raises novel issues which are of paramount importance to patients in psychiatric facilities who cannot defend themselves from non-consensual experiments which present a significant risk of harm and death and which may not even offer an iota of benefit."<sup>98</sup> Plaintiffs proceeded to repeatedly refer to "risky," "wholly non-therapeutic" experiments.<sup>99</sup>

The plaintiffs' papers also stated,

[T]he OMH experiments involve both "FDA approved and non-FDA-approved experimental antipsychotic and psychotropic drugs" and "highly invasive painful testing procedures" such as spinal taps, inhalation of radioactive gas, attachment to intravenous lines for several hours, radiation exposure, and skin biopsies . . . . The experiments are "capable of causing permanent harmful or even fatal side effects."<sup>100</sup>

Contrary to these assertions, to the best of our knowledge, in facilities operated or licensed by OMH, *no* studies are done that do not involve patient assent,<sup>101</sup> *no* non-therapeutic elements of any studies involve more than a minor increase over minimal risk, and there are *no* more than a minor increase over minimal risk studies that are "wholly non-therapeutic." The categorization of risk in human subjects research presents a number of complicated issues. However, utilizing generally accepted definitions,<sup>102</sup> *no* high-risk research is being carried out, to our knowledge, in OMH operated or licensed facilities. In addition, the procedures the plaintiffs refer to are all performed in the course of ordinary medical care in hospitals all over the country. They are not highly invasive, they are either not painful or are only minimally so, and the drug side effects referred to are those listed in the *Physicians' Desk Reference* as potential side effects of FDA-approved medications routinely prescribed in standard psychiatric treatment.

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of what happened in Nazi prison camps or Tuskegee exists' said Ruth Lowenkron, an attorney with New York Lawyers for the Public Interest who argued the case in State Supreme Court in Manhattan." *Id.* at 3.

98. Plaintiffs'-Appellants' Motion for Leave to Appeal, *supra* note 96, at 20.

99. *Id.*

100. *Id.*

101. Though the regulations contemplated the possibility that court authorization for treatment over objection could be sought to provide necessary treatment not otherwise available, we are not aware of any case in which such authorization has been sought.

102. See Evan G. De Renzo, *Decisionally Impaired Persons in Research: Refining the Proposed Refinements*, 25 J.L. MED. & ETHICS (1997).

#### D. *Shrinking the Category of Therapeutic Research*

While the litigation was proceeding, numerous attempts were made to settle the matter through face-to-face dialogue between the parties. One issue that was particularly contentious was how to characterize research that was expected to benefit participants and contained a non-therapeutic element. Plaintiffs insisted on rigidly categorizing every research protocol as either therapeutic or non-therapeutic. They defined any protocol, in its entirety, as non-therapeutic if any element of the protocol was non-therapeutic, thus significantly shrinking the category of research considered therapeutic.<sup>103</sup>

The consequences of this categorization are very significant. For example, protocols involving non-therapeutic uses of procedures such as Positron Emission Tomography (PET) scans, no matter how much potential benefit they otherwise offer, are classified as non-therapeutic because of such categorization. Although plaintiffs' basis for classifying research was never examined by the courts, the appellate division's decision effectively adopted their classification and banned all non-therapeutic, more than minimal risk research involving minors or incapable adults, unless such research is federally-funded.<sup>104</sup>

In New York, IRBs have traditionally been responsible for evaluating risk/benefit ratios of protocols, to assure that even if a protocol contains non-therapeutic elements, the overall benefits of the protocol outweigh the risk of the non-therapeutic elements in question.<sup>105</sup> Guidance was provided to the IRBs by the OMH regulations, which, for emphasis, repeated the federal requirements for approval of research.<sup>106</sup> The OMH regulations also provided that treatment teams must approve more than minimal risk research<sup>107</sup> and stipulated that incapable adults could only participate in research if it could not be done without their participation and only if the knowledge likely to be produced had overriding therapeutic importance for the understand-

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103. At one point in the litigation, before the appellate division decision, the defendants agreed to a stipulation reflecting this categorization in exchange for an amendment of the definition of "therapeutic." Stipulation of Feb. 9, 1996, 626 N.Y.S.2d 1015 (Sup. Ct. 1995) (Index No. 5136/91). This definition had included the language "and is only available in the context of research," which would have allowed only research involving investigational drugs and would have banned all research involving marketed drugs thus adversely impacting research seeking to establish lower dosage levels of medications. *Id.*

104. See *T.D. v. New York State Office of Mental Health*, 650 N.Y.S.2d 173 (App. Div. 1996), *appeal dismissed*, 680 N.E.2d 617 (N.Y. 1997), *leave to appeal granted* by 684 N.E.2d 281 (N.Y. 1997), and *appeal dismissed* by 1997 WL 785461 (N.Y. Dec. 22, 1997).

105. See N.Y. COMP. CODES R. & RECS. tit. 14, § 527.10 (1997).

106. See *id.* § 527.10(d).

107. See *id.* § 527.10(d)(3).



ing or treatment of a condition presented by the patient in question.<sup>108</sup>

Although we disagree with the plaintiffs' categorization of procedures like lumbar punctures or PET scans as "highly risky," it is true that these procedures might be viewed by some as acceptable if necessary diagnostic or therapeutic components of treatment, but not acceptable as non-therapeutic components of a research protocol, even if the protocol is otherwise therapeutic. However, the small degree of risk or discomfort caused by the non-therapeutic procedure is minimal in contrast to the substantial morbidity or mortality of the condition being studied (*e.g.*, schizophrenia, suicidal depression) and the anticipated benefit to the subject from the therapeutic aspects of the protocol that may be largely or entirely unavailable outside of the context of research.

Absent specific evidence of adverse consequences from the non-therapeutic use of common diagnostic procedures, absolutely banning their use unnecessarily impedes the development of better treatments, which is particularly unjustified given the overall benefits to research participants. If problems were to be identified regarding such use, tailored standards or mechanisms should be explored before an absolute legal ban is considered.

#### *E. Combining Rigid Categories and Risk Exaggeration*

Another fundamental difference between the plaintiffs and OMH concerned the use of the concept of a "minor increase over minimal risk."<sup>109</sup> Although this level of risk classification was proposed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research<sup>110</sup> and adopted in the federal regulations regarding research involving children,<sup>111</sup> the plaintiffs would not accept the concept. As a result, research posing only a minor increase over minimal risk was categorized along with highly risky research as simply "more than minimal risk" and thus banned under the court's ruling.

"Minimal risk" is defined in the federal research regulations to the effect that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than

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108. *See id.* § 527.10(d)(6).

109. THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN, DHEW Pub. No. (OS) 77-0004 at 8 (1997).

110. *See id.* at 7-9.

111. Protection of Human Subjects, 45 C.F.R. § 46.406(a) (1997).

those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."<sup>112</sup> The provisions in the federal research regulations concerning children permit research which is not expected to benefit the child and involves risk that is only a "minor increase over minimal risk" if certain conditions are met.<sup>113</sup> Although this risk level is not further defined by the regulations, its application to research involving minors includes an instruction to IRBs to evaluate the experiences ordinarily encountered by the subjects, including their experiences during the course of regular treatment, in making its determination about the risk posed by a research intervention to a particular subject population.<sup>114</sup>

Examples of elements in OMH protocols determined by IRBs to be non-therapeutic and more than minimal risk, which plaintiffs repeatedly referred to as "highly risky," are PET scans and lumbar punctures. We would argue that these procedures should be categorized as no more than a minor increase over minimal risk, an argument others make as well:

There are those who argue that . . . [LPS and PET scans] are, if not minimal risk, not more than a minor increase above minimal risk. Although LPS and PETs are not on the list of minimal-risk procedures contained in the U.S. research ethics regulations, Title 45, Code of Federal Regulations, Part 46 (45 C.F.R. 46), this list has not been updated in many years and these procedures may eventually be added.<sup>115</sup>

In fact, in New York, no more than minimal risk non-therapeutic research elements are carried out that we know of with the populations in question where the non-therapeutic elements present more than a minor increase over minimal risk to participants.

In its now invalidated research regulations,<sup>116</sup> OMH had attempted to supplement federal regulations and provide overall guidance to IRBs as they carefully weighed the risks and benefits of research protocols. OMH's goals were to require reasonable protection for patients while acknowledging their autonomy, yet at the same time to avoid setting barriers so high that they could block scientific

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112. *Id.* § 46.102(i).

113. *Id.* § 46.406(a).

114. *See id.* § 46.406(b).

115. Evan G. DeRenzo, *Surrogate Decision Making for Severely Cognitively Impaired Research Subjects: The Continuing Debate*, 3 CAMBRIDGE Q. HEALTHCARE ETHICS 539, 540 (1994).

116. *See* N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10 (1997).

progress —progress to benefit the very patients being protected. The plaintiffs' argument that research with children or incapable adults could be continued by simply deleting any non-therapeutic more than minimal risk elements disregards the realities of scientific research. Some vitally important questions can only be addressed by employing procedures that are not entirely risk-free but provide answers that could lead to important therapeutic benefits. Risk is encountered daily in routine health care, in the form of diagnostic evaluations to "investigate" the etiology of clinical symptoms. For example, procedures such as PET scans, angiograms, laparoscopies, or even "exploratory" laparotomies are carried out to search for the disease source, with no guarantee that positive findings will result. In our view, small increments of risk are at times necessary in the context of carefully conducted clinical research in order to find ways to relieve the extreme pain and suffering of severe mental illness.

#### IV. IMPACT OF NEW YORK LITIGATION

Unless corrected by the New York State Court of Appeals, the decision as now written by the New York courts will mean that some significant research that is currently being conducted on mental illness will not be able to continue, as illustrated in the following two examples:

1. A major academic department of psychiatry has a large portfolio of foundation-funded research.<sup>117</sup> Researchers at this institution recently described their plan to begin a sensitively and carefully designed PET brain-imaging study of autistic children.<sup>118</sup> Childhood autism is a pervasively disabling, severe condition. New findings are crucial to better understand this condition, and taking advantage of new non-invasive brain-imaging technologies makes eminent sense. The researchers had to be informed that because this study was non-therapeutic, it was now illegal in New York.

2. At NYPI, a study is being carried out of suicidal adolescents. Suicide is the second leading cause of death among adolescents age 15-19, and it has increased by over 300% since 1950 in this age group.<sup>119</sup> Studies in adults have revealed low central nervous system

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117. Personal communication between David Silbersweig, M.D., Cornell Medical College, and John Oldham, M.D., Director, New York Psychiatric Institute (March 26, 1997).

118. *See id.*

119. *See* Alan L. Berman & David A. Jobes, *Suicide Prevention in Adolescents (Age 12-18)*, 25 *SUICIDE & LIFE THREATENING BEHAVIOR* 143 (1995).

serotonin levels in certain patients at highest risk for suicide.<sup>120</sup> Other studies, however, have established that one cannot automatically apply findings that hold in adults to younger populations.<sup>121</sup> The study in question involves hospitalizing highly suicidal youngsters at NYPI, and providing at no cost to them, several months of enormously therapeutic intensive inpatient treatment.<sup>122</sup> These minors assented to participate in the research, and their parents gave informed consent.<sup>123</sup> A crucial component of this study is the performance of a lumbar puncture, or spinal tap, a diagnostic procedure, of which the main risk is that, in about ten to fifteen percent of cases, it causes a bad headache, which usually subsides within twenty-four hours.<sup>124</sup> It is a test that is carried out every day in every general hospital. Because this more than minimal risk procedure is non-therapeutic, the entire study is categorized as non-therapeutic and was suspended due to this litigation. Only because federally-funded studies were exempted and this study is part of the research program in a National Institute of Mental Health-funded Child Center grant, could this study be resumed. If the plaintiffs were successful in their attempt in the court of appeals to halt such federally-funded studies as well, this research project would have been prohibited. It is clear from plaintiffs' letter to the *New York Times*,<sup>125</sup> that they expected the *T.D.* litigation to impact all medical research. Thus, for example, if a child developed leukemia and the parents of the child wished to enroll their child in a treatment research protocol involving a promising new medication not yet otherwise available, the parents would be unable to do so if the study

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120. See Peter Nordstrom et al., *CSF 5-HIAA Predicts Suicide Risk After Attempted Suicide*, 24 SUICIDE & LIFE-THREATENING BEHAVIOR 1, 2 (1994).

121. See Benedetto Vitiello & Peter S. Jensen, *Medication Development and Testing in Children and Adolescents: Current Problems, Future Directions*, 54 ARCHIVES GEN. PSYCHIATRY, 871-76 (1997).

122. See Biological Studies in Suicidal Adolescent Inpatients, Fed. Grant No.3 Rol MH 47113-0451 (unpublished protocol on file with co-author John Oldham, M.D.) This multi-site treatment study sought to study the effects of some antidepressant medications on children diagnosed with depression, suicidal tendencies, or anxiety. See *id.* at 113. The NYPI inpatient research ward supplied "all supportive inpatient services, including psychological assessment, close nursing care, and careful medical supervision." *Id.*

123. See *id.* at 113. "Both parent and adolescent are provided with their own consent forms, and both must sign before the study begins." *Id.* There are "two safeguards" established by this protocol: 1) both must sign the consent form, and 2) "the adolescent has at least a week between the time of signing consent and the beginning of the biological tests to change his or her mind." *Id.*

124. See ROBERT A. FISHMAN, *CEREBROSPINAL FLUID DISEASE OF THE NERVOUS SYSTEM* 172 (2d ed. 1992).

125. Letter from Cliff Zucker et al., to Editor, N.Y. TIMES, January 7, 1997, at A16.

included a non-therapeutic element such as a bone scan. Such a study would be illegal in New York State.

Throughout the litigation, the defendants attempted to impress upon plaintiffs the adverse impact on research that would occur if they prevailed. At one point we presented them with a hypothetical example<sup>126</sup> in the hopes that they would at least recognize the problematic consequences of the rules they sought to establish. The hypothetical situation involved a medication X, a new anti-psychotic agent that is thought to be very effective if treatment commenced immediately following acute onset of the illness. The research would include individuals in their early twenties, thus unlikely to have executed advance directives, suffering from levels of disability that would likely render them incapable of giving informed consent. The relative safety of X has been established in FDA-regulated Phase I/II trials, and an IRB is considering a Phase III pilot protocol to study the degree of efficacy. A brain scan or lumbar puncture is needed to understand X's locus of action in the brain and its metabolic impact on the patient's health and on the disease processes, in order, ultimately, to develop the next generation of safer, more effective medication. Such procedures were necessary to complete the development of medication X and to obtain its FDA approval. The rules which plaintiffs seek to establish would absolutely prohibit this research.<sup>127</sup>

## V. CONCLUSION

Research must be done in a careful, thoughtful, and heavily reviewed and scrutinized way. It must be done ethically and respectfully, attending to patients' rights. These critical concerns, however, must be integrated with the need to make available promising treatments for devastating illnesses as well as the need to continue the development of better treatments, which can only be discovered through research. A plan like the Maryland proposal accomplishes such a desirable balance. Unfortunately, the results to date of the court process in New York do not, in our opinion, achieve this goal.

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126. Letter from Stephan Haimowitz to Cliff Zucker, attorney representative for plaintiffs, also working with public service law office serving persons with mental and physical disabilities and Ruth Lowenkron (November 1, 1995) (copy on file with co-author Stephan Haimowitz, J.D.).

127. When presented with this scenario, plaintiffs responded that the problem would rarely arise because such studies could probably be done with patients who were capable or had executed advance directives, but if not, the research should be banned, regardless of the consequences. Telephone conversation between Stephan Haimowitz, Cliff Zucker and Ruth Lowenkron (November 21, 1995).