Editorial

The Challenge to Psychiatry as Society's Agent for Mental Illness Treatment and Research

Society has a moral responsibility for its sick and disabled citizens. Psychiatry assumes this responsibility when clinicians provide care and treatment to mentally ill patients, many of whom suffer from the worst diseases afflicting humans. But these very patients often lack insight into the nature of their afflictions, their causes, and their need for treatment. Experiencing altered perceptions, affects, and beliefs is very different from experiencing other somatic dysfunctions. Both patients and society view the latter as illness requiring medical intervention, whereas the former all too often are viewed as personal attributes rather than disease. Society is uncertain how to assert responsibility, looking simultaneously to law enforcement, religion, psychiatry, the family, and social planning. Given complex and competing themes, psychiatry's capacity to assert and validate illness models and therapeutic interventions is invaluable. A major advance over the past 40 years has been establishing society's confidence that psychiatry can identify individuals who suffer from mental disorders and intervene with effective therapeutics. At the same time, society has also advanced the cause of civil liberties for the mentally ill. Here, too, much good has been accomplished, but disquieting problems remain, problems that stir passions as the ethics and politics of personal autonomy and free will clash with the consequences of honoring these virtues.

Gardner and colleagues tackle a vexing paradox in this issue of the *Journal*. Psychiatry accepts a clinical responsibility for determining which individuals, on the basis of mental disease and law, shall be deprived of autonomy rights and dignity by involuntary commitment to receive protection and (perhaps) treatment through clinical services. This burden of judgment and responsibility weighs heavily on the physician-patient relationship and on the professional identity of the physician. Psychiatrists experience their discipline at risk when their assertion of this authority is criticized by society and by the patient whose autonomy rights are compromised. Nothing is quite as reassuring in the exercise of this responsibility as a grateful patient who has come to appreciate the physician's action. Stone's "thank you" theory (1) captured this important dynamic and has been used in support of psychiatry's wise exercise of this authority.

Gardner and colleagues tested the theory's validity with empirical data. They found that many patients who did not believe that hospital admission was needed entered as voluntary patients anyway. There is room for negotiation when physician and patient have discordant views. Patients who did not believe that they needed hospitalization but who believed they had a mental illness and accepted voluntary admission were most likely to change their view and agree that a need for hospitalization existed. However, patients who denied that they had a mental illness, felt coerced, and entered as involuntary patients most often sustained their view that hospital care was not needed. The "thank you" from these patients remained theoretical. Most of the patients in this study were given affective or "other" diagnoses, and substance abuse was common. It is uncertain how these results generalize to more specific populations where insight is commonly impaired (e.g., patients with schizophrenia or mania), but results are not likely to be more gratifying.

Psychiatrists most often must accept the responsibility of denying autonomy and dignity rights without the appreciative endorsement of their patients. Clear role definition regarding clinical and social responsibility, valid concepts and assessment procedures to meet legal and clinical standards, and an acceptable degree of predictive validity regarding safety and therapeutic advantage are essential. Most important is that society sanction this role assigned to the psychiatrist in addressing the moral obligation of protection and treatment for the very ill citizen. However, the tension will remain as long as the patients we serve fail to understand their illness and the physician's purpose. Change in this regard is importantly dependent on new therapeutic advances through scientific research.

The role of the psychiatric investigator in meeting society's obligation to develop new knowledge to benefit ill citizens is also a vexing paradox: society simultaneously expresses "best hope" and "worst fear" images. No responsible commentator doubts that new knowledge through science is critical to advancing treatment and prevention of mental illness, but current attention in the popular media involves harsh criticism of psychiatric investigations (2–11). Clinical research is not a perfect endeavor, and errors in subject protection procedures and occasional fraudulent investigators have been noted. Much of the criticism, however, is based on misunderstanding of science, misrepresentation of facts, and unsubstantiated allegations. Nonetheless, there is a common ground of concern on the issue of the capacity to make decisions in providing informed consent to research participation.

Subjects in mental illness research are usually presumed to be competent. This may be viewed as respect for the autonomy and dignity rights of persons with mental illness, but the question has also been raised that the presumption of competence permits too many patients with impaired decision-making capacity to sign consent forms they do not understand. Those who believe that valid informed consent can be (and usually is) obtained believe that optimal procedures require continual evolution and that better documentation is needed to enable society to judge the adequacy of the informed consent process. Those who believe that mental illness research is substantially conducted without valid informed consent doubt that investigators and institutional review procedures can ever ensure that this lynchpin of ethical research will be routinely secured. All agree on the urgent need for data that address decision-making capacity for providing consent among prospective subjects for mental illness research. It is here that Appelbaum and colleagues make an important contribution of empirical data in this issue of the *Journal*.

Using an experimental, but carefully constructed, assessment of decision-making capacity, Appelbaum and colleagues found that depressed patients in a clinical trial had largely unimpaired decisional capacity and, therefore, were likely to be able to exercise their right to self-determination regarding research participation. Moreover, the patients maintained this capacity over time, suggesting that they remained able to exercise important elements of informed consent such as a sustained understanding of the purpose of the research and the right to withdraw. Appelbaum et al. report that decision-making capacity was not significantly related to severity of depression, a finding compatible with the commonplace observation that many psychiatric patients maintain competence for most aspects of everyday life despite severe symptoms. This study involved moderately depressed outpatients. It is not certain how these results apply to more severely depressed or psychotic patients.

Adequacy of informed consent in psychiatric research was the leading issue when the National Bioethics Advisory Commission addressed subject protections in mental illness research (12). The commission's focus on the mentally ill was not based on evidence of informed consent deficiencies or other abuse of subject protections that distinguished psychiatric research. Nonetheless, the commission made its report and recommendations on mental illness rather than a broader consideration of brain dysfunction, which increases risk for cognitive impairment, or a narrow consideration of individuals who actually lack decisional capacity for the purpose of informed con-

sent. The commission made recommendations for regulatory redress in psychiatric research alone. In testimony to the commission, Dr. Appelbaum presented data from the depression study reported in this issue of the *Journal* and similarly reassuring data that most subjects with schizophrenia at the Maryland Psychiatric Research Center were able to achieve decision-making capacity similar to that of normal control subjects when participating in an educational informed consent process. Dr. Appelbaum's view that problems that could be documented should be addressed with solutions that had been tested and subjected to a cost-benefit analysis was not apparent in the recommendations of the National Bioethics Advisory Commission. The result, at least in part, is another expression of society stigmatizing the mentally ill and those who serve them.

I am concerned that more harm to the future of individuals with mental illness is being caused by the rush to allegation and redress than is justified by anticipated benefit. Optimal and ever-evolving procedures for the protection of research subjects, including the mentally ill, are of fundamental importance. Stigmatizing those citizens who receive a psychiatric diagnosis, however, and creating a veil of mistrust between society and psychiatric investigator can be rationally justified only if research procedures in psychiatry are both unique and flawed. Commissions in New York (13) and Maryland (14) recently addressed issues of subject protection in medical research with populations at risk for impaired decision-making capacity. Michels (15) called attention to the substantial difference in tone and content of the New York and Maryland commissions compared with the National Bioethics Advisory Commission report, and the interested reader will see this contrast extended when reading the companion articles by Michels (15) and by Capron (16), a member of the national commission. Michels suggested that the failure of the national commission to include any member with experience and expertise in psychiatric research may explain the difference. In this regard, the two state commissions focused on the decision-making capacity of individuals rather than diagnostic groups, on investigator and review procedures that would enhance capacity assessment and ensure adequacy of consent, on how to design protections in a more realistic relationship to risk, and on how to avoid costly new procedures that would interfere with acquisition of knowledge unless evidence for need and effectiveness was presented. Involvement of psychiatric investigators in these two commissions also reflects the field's commitment to examining problems and evolving optimal procedures.

The psychiatric investigator lives in interesting times. Although I believe much of the present public attention is ill-informed and unfair, the field has received a wake-up call. Adequate decision-making capacity for providing informed consent to research participation can be assessed and documented. But how well is this being done in all the various settings where research is conducted? What constitutes adequate capacity, and how is this to be determined and documented? Who should participate in informed consent, and how should research be conducted if the person is judged to be too impaired for competent consent? How should these procedures be reviewed, and which stakeholders should participate in the review? These and many other questions are on the table. As they are addressed in new federal procedures and regulations, there is already much to do at the local level to address subject protections. The following suggestions seem reasonable, helpful, not too demanding, and protective of both patient subjects and investigators. Not intended as comprehensive guidelines, these suggestions illustrate actions that can be initiated by clinical investigators and their institutions and have worked well at the Maryland Psychiatric Research Center.

1. Have patients or their advocates comment on proposed research and consent forms.

2. Ensure that informed consent is an educational procedure taking place in a time frame that enables the prospective subject to understand, appreciate, reason, and freely exercise choice.

3. Include clinicians other than key investigators in the informed consent process and assessment of decision-making capacity, but do not exclude the investigator from personal responsibility and participation.

4. Include significant others as the patient considers participation, but do not compromise the patient's autonomy and dignity rights if decision-making capacity is adequate.

5. Provide material to all concerned clarifying that clinical care involving research is importantly different from ordinary clinical care. Work with patient subjects to minimize the therapeutic misconception that is commonplace in biomedical research (17).

6. Ensure that patient subjects have contact with a noninvestigator who can help resolve issues relating to research participation.

7. When accepting a consent form, document understanding of basic facts relating to the protocol (the Maryland Psychiatric Research Center administers an evaluation-of-signed-consent test [18]).

8. Provide educational and sensitivity-raising sessions in ethics for investigators and staff. Include an appreciation of the fundamental role in subject protection incorporated in institutional-review-board-related procedures.

This last point merits brief comment. The media and a handful of severe critics have taken findings of procedural errors and reported them as unethical research and implied that unethical scientists are harming patients (2–11). This I condemn, but clinical investigators have also sometimes regarded such findings as merely procedural. We need to inculcate a deep appreciation of the regulations for review and approval and the monitoring of research as fundamental to the protection of human subjects. These procedures must be conducted with care, and shortcomings must be addressed as a first priority in the ethical conduct of human research.

REFERENCES

1. Stone AA: Mental Health and Law: A System in Transition. Rockville, Md, NIMH Center for Studies of Crime and Delinquency, 1975
2. Hilts PJ: Agency faults a UCLA study for suffering of mental patients. New York Times, March 10, 1994, p A1
3. Hilts PJ: Medical experts testify on tests done without consent. New York Times, May 24, 1994, p A13
4. Hilts PJ: Consensus on ethics in research is elusive. New York Times, Jan 15, 1995, p 24
5. Hilts PJ: Psychiatric researchers under fire for experiments inducing relapse. New York Times, May 19, 1998, p C1
6. Hilts PJ: Psychiatric unit's faulted. New York Times, May 28, 1998, p A26
7. Wilwerth J: Tinkering with madness. Time, Aug 10, 1993, pp 40–42
8. Whitaker R, Kong D: Testing takes human toll. Boston Globe, Nov 15, 1998, p AO1
9. Kong D: Debatable forms of consent. Boston Globe, Nov 16, 1998, p AO1
10. Whitaker R: Lure of riches fuels testing. Boston Globe, Nov 17, 1998, p AO1
11. Kong D: Still no solution in the struggle on safeguards. Boston Globe, Nov 18, 1998, p AO1
12. Research Involving Persons With Mental Disorders That May Affect Decisionmaking Capacity, vol I: Report and Recommendations of the National Bioethics Advisory Commission. Rockville, Md, NBAC, Dec 1998
13. New York State Department of Health Advisory Work Group on Human Subject Research Involving the Protected Classes: Recommendations on the Oversight of Human Subject Research Involving the Protected Classes. Albany, New York State Department of Health, 1998
14. Final Report of the Attorney General's Working Group on Research Involving Decisionally Incapacitated Subjects. Baltimore, Office of the Maryland Attorney General, 1998
15. Michels R: Are research ethics bad for our mental health? N Engl J Med 1999; 340:1427–1430
16. Capron AM: Ethical and human-rights issues in research on mental disorders that may affect decision-making capacity. N Engl J Med 1999; 340:1430–1434
17. Appelbaum PS, Roth LH, Lidz CW, Benson P, Winslade W: False hopes and best data: consent to research and the therapeutic misconception. Hastings Cent Rep 1987; 17:20–24
18. DeRenzo EG, Conley RR, Love R: Assessment of capacity to give consent for research: state of the art and beyond. J Health Care Law and Policy 1998; 1:66–87

WILLIAM T. CARPENTER, JR., M.D.

Address reprint requests to Dr. Carpenter, Director, Maryland Psychiatric Research Center, P.O. Box 21247, Baltimore, MD 21228.