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Some Current Factors Influencing the Prescribing and Use of Psychiatric Drugs

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Synopsis

A reprise of selected known factors about the influences affecting the prescribing and use of drugs, and some new developments in the drug marketplace, are the basis for this summary and observations about future expectations regarding psychotherapeutic agents. This information can be used to assist in formulating or updating, or both, conceptualizations and hypotheses for future policy and research planning in this area.

IN THE 1970S MANY PUBLIC INSTITUTIONS for the mentally ill were emptied of large numbers of patients. Following the advent of new and powerful antipsychotic drugs and other psychotherapeutic agents useful in maintenance therapy, the likely control of patients' symptoms and their destructive behaviors toward self and others was possible. Accordingly, psychotropic drugs, halfway houses, and local outpatient treatment resources were often used in combination with the intent of integrating patients back into local communities and family settings as a putatively more effective and humane therapeutic alternative to long-term warehousing of the mentally ill.

Interest in these drugs and psychotherapeutic agents has continued relative to certain variables of importance that influence the process of drug prescribing and use. Some of these variables have been previously identified and reported (*1*). They include information resources such as professional journals, reference texts, peers, and clearinghouses; the nature, extent, and presenting symptoms of disorders and illness; an assessment of available alternative treatment interventions and their cost benefit to risk analysis (*2*); patient characteristics (*3-5*); physician-prescriber attributes such as age, sex, type of practice, and treatment orientation (*1*); prescriber-patient relationship (*6-8*); and others.

The purpose of this paper is to reprise and update information about some of the more well-known influence factors and to report selected new developments in the pharmaceutical industry, drug marketplace, sociopolitical and regulatory spheres, and certain elements in the health-medical care system, in order to present a synthesis of selected outcomes or effects that may occur from their interrelationship or interaction in the process of psychotherapeutic drug prescribing and use. Summary observations are offered about how some of these factors may influence the future direction of drug prescribing and use of psychotropic agents in the United States. It is hypothesized that this approach to interdisciplinary conceptualization will facilitate policy planning and the design and conduct of future research—research that can provide findings with heightened explanatory power useful in understanding problems related to psychotherapeutic drugs.

Psychotherapeutic Agents

The experience of both provider and consumer with drug products appears to influence decisions about drug prescribing and use. In fact, many of the positive and negative factors identified from experiential use with psychotherapeutic agents are now well known. Examples of their limitations include serious and sometimes irreversible side effects such as tardive dyskinesia (*9*), abuse liability of a particular agent (*10*), issues regarding limitations of design and methodology in some clinical drug studies and evaluations (*11*), and cost of some medications (*12,13*). In contrast, although the comparative analysis of pharmacotherapy and psychosocial approaches to the treatment of mental illness are still being discussed (*14,15*), psychopharmacotherapy may lead to reduction of symptoms to enable social skills training and learning applications to improve patients' social performance (*16,17*). On balance, the advantages of proper drug administration and use seem to outweigh disadvantages for most patients (*18*) in treatment for symptoms of mental disorders.

Now a new and potentially important breakthrough in the evolutionary development of psychotropic drugs requires attention. This is the advent of a pioneering generation of biotechnology-derived and -produced agents (*19*) with a likely new tier of price structuring and as yet unknown effects upon medication prescribing and use. Counting all disease and therapeutic product categories, as of 1990, a total of 14 biotechnology drugs were reportedly in the final clinical trials stages, and nearly 80 agents were in some stage of Food and Drug Administration testing while a small number of biotechnology drugs have been approved (*20*).

Contemporary Changes and Advancements

Changes in factors that influence the prescribing and use of psychotherapeutic medications reportedly have not occurred in isolation but rather can be associated with contributory historical developments and the evolution of contemporary psychiatry. I cite, for example, the resurgence of moralistic norms and values regarding ethical treatment needs in social psychiatry, experimental and clinical drug research and use, provision of baseline experience and knowledge about increasing numbers of powerful new drugs for mental health-related purposes, and the trends toward deinstitutionalization of the mentally ill and mentally retarded that have been facilitated by applicable advances enabling outpatient drug maintenance therapy using psychotropic agents (*21,22*). Now, contemporary advancements in drug biotechnology, and the trend in emphasis upon neuroscience and biological psychiatry, brighten the prospects for a scientific dimension and legitimacy heretofore not unanimously accorded psychiatry (*23*). These developments could bolster the standing of the mental health field and improve related coverage offered by health insurers (*24*). Such a heightened status might well have significance as a factor influencing future prescribing and use of psychotherapeutic agents.

Physician Allocator and Gatekeeper

Court decisions, with few exceptions, have generally reinforced the key drug-related influence role and authority of physicians that has evolved from socio-historic sources such as statutory and common law plus the 1938 shift in prescription drug status in the United States (*25,26*). Orientation to drug therapy and prescribing practices is commonly circumscribed within the medical school curriculum or internship experience and is frequently an integral component in the applied medical practice of various specialists. Nevertheless, some diminution in the prescribing influence role of physicians has been noted in attempts to regulate such aspects of psychiatric practice as drug therapy (*27*). Another newly important development is the phenomenon variously described in some general conversations

and anecdotal accounts as defensive prescribing. In the absence of scientific documentation, this putative response to concerns about medical malpractice litigation and the increasing costs of insurance coverage needs to be validated and explored through investigation and findings of empirical research to establish the magnitude of its influence on prescribing.

Consumer-Patient

The increasing importance of consumers' influence on health care providers has been reported (*28*). Unquestionably, some prescribers are being influenced to write patient drug prescriptions they would not issue otherwise as a result of institutional advertising and a new drug industry trend of direct consumer advertising in magazines, newspapers, and some television commercials (*24*). Moreover, there is a reported strengthening of consumer self-medication practices (*29*). In addition, the formation, role, and popularity of self-help groups, particularly in the mental health arena (*30*), is another factor to consider because of the influence of these groups on the drug prescribing process as well as the demographic shift to an older population of patients who already consume a disproportionate share of medications.

Food and Drug Administration Influences

Current key issues involve expressed concerns about agency independence versus politicization and continuing regulatory delays (*31*). In the early 1980s, recision of the agency's authority to issue regulations resulted in the addition of bureaucratic layers of oversight and review from the Department of Health and Human Services and the Office of Management and Budget, allegedly to the regulatory detriment of drug, food, and other products (*31*). A surge is expected in the number of investigational new drug applications and abbreviated new drug applications for generic products (185 drugs lose their patent protection by 1995 while 3 to 10 companies are expected to file applications for each of these) while the agency is experiencing a shortage of personnel, obsolete equipment, and poor working conditions as identified by a blue-ribbon committee looking into the agency's problems (*32*). Agency program reform and restructuring are being used to address problems uncovered in the recent generic drug scandal (*33*). Selection and installation of a new Commissioner has been completed. Nevertheless, these problems critically impact various product areas regulated by the agency including psychotherapeutic agents (such as fluoxetine, now America's most prescribed antidepressant with forecasted sales of $500 million in 1990 and $1 billion by 1995) (*24*).

Manufacturer and Marketplace Influences

Within the context of increased competition among manufacturers (associated with higher costs of drug research and the heightened necessity of competing on a global scale to realize favorable economic benefits) (*34*), and additional scrutiny from Congress, regulatory agencies, and the public regarding quality assurance and cost containment pressures, some innovations in manufacturers' response to marketplace conditions are noteworthy. These include the following examples.

- At least one company has challenged the Food and Drug Administration's taboo on consumer advertising without the mandatory listing of contraindications for drug use (*35*)—a challenge which at the time was expected to accelerate with wide-open consumer drug advertising within the next 18 months (*36*).
- The current periodic use of institutional advertising (nonbrand specific) could ease the transition into direct consumer drug advertising on radio and television.
- A spate of drug company mergers and acquisitions has resulted in an increased presence of consolidated multinational pharmaceutical manufacturing and marketing conglomerates.
- Agreements have been reported between certain innovative research-intensive drug houses and over-the-counter marketing firms to speed marketing of what are currently prescription drugs with prestigious brand names (*29*) thereby seeking to protect some of the trademark benefits provided by the patent.
- Some companies have increased professional detail (sales) personnel by more than 25 percent within the last year with the formation of expert teams who promote drugs only to certain specialists (psychiatrists or internists, for example) in order to increase their prescribing and use of company drug products (*36*).
- Provision of some pharmaceutical manufacturer promotions, and educational and economic-related incentives for drug prescribers and medical students, within a climate of public opinion surrounding ethical concerns about conflicts of interest and normative guidelines for professional behaviors.

'Many of the factors that influence psychotherapeutic drug prescribing and use are circumscribed by a framework of increasing health care costs and counter demands for their control and reduction.'

Pharmacists

The import and added influence value which pharmacists and pharmacy may exert on drug prescribing and use, as the profession specifically trained in drug knowledge and expertise, has been newly reinforced in findings of a draft report from a landmark Federal study (*37*). The pharmacists' role in drug therapy management can be critical for patients with complex drug regimens and drug prescriptions from multiple prescribers. For example, the pharmacist's knowledge of the patient, his or her medical history, and risk factors such as possible adverse drug interactions or other contraindications for use, can be of paramount importance in preventing the inappropriate and unsafe dispensing of medication.

Accordingly, as a key liaison and source of influence with patients-consumers and physicians regarding drug prescribing and use, pharmacists can and should assume a more active professional role in patient counselling rather than carrying out a solely drug dispensing function (*38*). Thus some see the pharmacy as returning to its earlier emphasis on counselling and communicating with patients (*39*), not infrequently in special areas of new retail stores established at least in part as a possible deterrent response to potential customer erosion from an expanding prescription drug mail order business (*39*). Some pharmacists have established private practices offering in-depth counsel relative to all aspects of patient medication use (*39*). Pharmacists are opportunistically positioned to influence drug prescribing and use, particularly regarding categories of controlled substances in the psychoactive drug product area. Findings from a newly reported research study showed a predictive association between illicit drug use and psychotherapeutic medicine use, independent of psychiatric symptoms among drug users (*40*).

A proposal reportedly favored by some pharmacists, the American Pharmaceutical Association, and a consumer action group (but opposed by some drug manufacturers), would create a new class of nonprescription products available only from pharmacists (*41*). Florida reportedly permits pharmacists to dispense a few pharmaceuticals that are available only by prescription in other States (*39*).

Discussion

In order to analyze and assess current and future consequences associated with specific factors that influence drug prescribing and use, the interrelationship and interaction between selected factors and changing structural and functional aspects of the traditional health care services system need to be recognized as interconnected. Health care is a lucrative American business, and because of the nature of its product, combined with the unique interaction of other economic variables in the health care market place such as supply, demand, and pricing, it has been permitted to ignore the economic tenets that restrain virtually every kind of industry in the United States (*42*).

Doctors and hospitals have a competitive advantage in the marketplace in their ability to create demand and sell products and services merely by telling ill persons they need them (*42*). Furthermore, laypersons are frequently incapable of assessing medical intervention decisions to determine whether or not they are based upon medical necessity rather than primarily considerations of profit (*42*). Accordingly, physicians and hospitals have received payments pretty much in relation to what they ask for (*42*), although the sociopolitical risks of this approach appear to be increasing.

Moreover, in the drug market, the person who makes a product purchase decision is a different person than the consumer who pays for the drug and who cares more about the cost (*43*). There is little doubt that too many health care products and services are ordered unnecessarily and inappropriately (*44*). Nevertheless, given political uncertainties and the access that political action committee funds have purchased in Washington for physician, hospital, insurance, and pharmaceutical interests (*45*), the timing, nature, form, and extent of reforms remains to be seen. To date, in the health care system there has been movement from an office-based solo practitioner, the sole prescriber who is fee-for-service oriented, to professionally managed care groups that include such entities as health maintenance organizations, preferred physician providers, and nursing homes. These employ economic incentive programs to contain prescription drug and other escalating health and medical care

costs while at the same time addressing quality assurance issues and benefit coverage for specialty areas such as mental health and drug addiction. Extensive expansion of managed care or other business and consumer solutions must occur unless there is to be massive government regulation of health programs, insurance, and health care as well (*42*), including drugs.

Many of the factors that influence psychotherapeutic drug prescribing and use are circumscribed by a framework of increasing health care costs and counter demands for their control and reduction. Among the issues are the high costs of drug research and development, the upward spiral of cost-push inflation reflected in the rising drug price index (*43*), related medical-legal liability issues, and pharmaceutical industry mergers and acquisitions. Competition in the pharmaceutical marketplace (with the exception of special product categories such as orphan drugs) is a factor that may stimulate developmental research, help control prices, and influence selection of strategies and methods for manufacturing, marketing, promotion, education, and product monitoring. If a cyclical slowdown in mergers and acquisitions extends to the pharmaceutical industry, following their near record frequency in the corporate sector, some benefits derived from diverse competition may at least be partially realized.

Furthermore, niche marketing to satisfy special needs of target audiences (*46*), such as, for example, development and promotion of pharmacotherapeutic agents for treatment and symptom control for Alzheimer's disease and Huntington's disease that are more common among the elderly, can be expected to emerge as an increasingly important approach that influences the prescribing and use of psychotherapeutic agents. In addition, creation of academic centers of excellence, such as the Center for Neurosciences in the new research facility at the University of Colorado Center for the Health Sciences (*47*), will likely nurture achievements that may positively influence future prescribing and use of psychoactive drugs.

There are other factors that appear to be affecting the process of drug prescribing and use. Examples include

- possible extraction of drug manufacturer rebates to the Federal Government for drugs prescribed through Medicaid, a provision of a congressional budget deficit reduction plan regarding an important source of drug company business (*48*);
- other cost containment measures that increasingly are transferring medical decision making from physicians and patients to outside reviewers (*49*) such as utilization review and use of drug formularies by various managed care providers, associations, and some State programs; and
- several upcoming expirations of prescription drug patents which provide exclusive manufacturer rights (*43*) (it is noteworthy that some view the existing patent policy system as antiquated and a disincentive for rapid innovation in explosive growth fields such as biotechnology) (*50*).

Accordingly, in spite of a recent scandal involving limited segments of the generic drug industry and an agency of government, some manufacturers are competitively positioned to realize further benefits which may accrue from these factors in an already cost-conscious expansionary market for generic products (*34*).

A related influence factor is the trend toward home health care associated with hospital cost containment pressures. Expenditures for home health care drug therapy, as a replacement or adjunct to extended hospital care and surgery, are expected to rise from $2 billion plus in 1990 to around $7 billion in 5 years for mail order drugs (*51*). Although approximately $10 billion of maintenance or repeat-use drugs, excepting those prescribed for Medicaid patients, was funded by drug benefit plans in 1990, maintenance drug costs are expected to surge to $27 billion by 1995 (*51*). One important component of this target audience are persons ages 65 and older who, along with persons ages 10 and younger, are the highest users of prescription drugs and the population segments that are increasing the fastest (*52*). Both groups include consumers of psychoactive drugs.

In spite of industry profitability and escalating pharmaceutical prices, there has been a sharp decline in drugs as a percentage of American medical expenditures (7 percent in 1991 compared to 16 percent in the 1960s) (*43*). Additionally, there is some limited evidence based on preliminary data indicating that selected segments of the American public are manifesting more conservative attitudes toward use of psychotherapeutic medications, at least with regard to use of the subcategory of anxiolytics by a majority of persons with high anxiety levels in a southern community (*53*). Also, other available information highlights health problems and adverse drug events that some consumers experience when using a particular psychotropic drug product or certain classes of such agents (*24*).

In light of the expectation of many consumers

for timely, cost effective, widely available prescription drugs that are guaranteed to be safe and efficacious, interest by some manufacturers, consumers, and providers in direct consumer advertising has continued to mount. However, some recent regulatory and enforcement oriented statements and an attitude expressed by the new Commissioner of the Food and Drug Administration (*54*), indicate little likelihood of a quick stimulus to drug prescribing and use through direct consumer advertising (with the limited exception of drugs of singular effectiveness not well known to the public). In contrast, the agency's continuing interest in improving the new drug approval process could facilitate future drug prescribing and use by permitting review of new drug applications using private contractors, lifting key regulations controlling pharmaceutical research, creating a "fast-track" approval channel for drugs targeted to treatment of life-threatening illnesses, and investigating acceptance of drug approval decisions by other countries (*55*).

Some other selected influences on future drug prescribing and use include possible increases in the populations of both patients and prescribers. Physicians actively practicing medicine in the United States are projected to increase 22 percent relative to the population by the year 2000 (*56*). There is a prospect of extending the psychopharmacotherapeutic product prescribing franchise to clinical psychologists (an experimental training program is in process at Walter Reed Army Medical Center in Washington, DC) (*57*) and to pharmacists for a new limited category of drug products (*41*) (widespread approval and general acceptance of these two initiatives could have some noticeable impact on future drug prescribing and use, although a gradual and measured State by State response seems more politically tenable).

Coverage of 33 million uninsured Americans in some health insurance plans (*58*), a prime target market, could collectively boost drug prescribing and use. Public acceptance of the newly available biologically derived agents is not known, in part because they are likely to be costly, at least in their introductory phase. There is a probable time lapse before consumers derive economic benefits from this innovative manufacturing process, and potential third-party coverage problems indicate a cloud over too much optimism about biotechnology's short-term potential and impact, excluding possible breakthrough "wonder" drugs (*59*).

American drug manufacturers may not find European markets the ready source of new revenues which they provided in the 1980s because of such issues as trade barriers, differing government regulations, and currency exchange rates (*43*). In contrast, some European and Japanese pharmaceutical manufacturers are expected to establish or increase their presence in the American drug market by purchasing American companies or through other business arrangements such as joint ventures or licensing (*60*).

In summary, accurate and more definitive predictions about the future direction of psychotherapeutic drug prescribing and use, overall and by subcategory, will be revealed in time by the conduct and findings of empirical research and policy analyses. Nevertheless, the future prescription drug market and overall seemingly favorable prospects for psychotherapeutic agents will likely be subject to influence factors associated with a litany of pressures from special interest groups and competing constituencies of the socio-medical-legal-political spheres (*58*). These influence factors impact the prescription pharmaceutical sector, the prescribing and use of drug therapeutic category products such as psychotropic agents, and the applied health care setting. Thus monitoring and analysis of selected influence factors, in drug prescribing and use, is important and should be a continuing focus of ongoing research and investigations.

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