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The elderly and drug policy: coming of age

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Prologue: When the subjects of prescription drugs and the elderly population intersect, an array of issues emerges spanning the worlds of science, politics, and economics. It is a complicated subject that does not easily generate public policies to balance the often conflicting issues that present themselves. The overview of this thematic issue on prescription drugs and the elderly underscores this complexity by focusing on the geriatric dimension of drug development and regulation, the participation of the elderly in clinical research trials, pharmaceutical pricing, drug utilization, medication use in long-term care, the study of drug effects in aging, and the role of federal agencies in shaping policy on drugs and the elderly—a role briefly in the spotlight during congressional consideration of a Medicare benefit to cover the costs of catastrophic acute illnesses.

The author, Jerry Avorn, holds a medical degree from Harvard University and is one of very few academically affiliated physicians specializing in the complex relationship between prescription drugs and the elderly. An internist and a geriatrician, Avorn is an associate professor at Harvard Medical School and is a member of the Gerontology Division of one of Harvard’s teaching hospitals, Beth Israel, where he directs the Program for the Analysis of Clinical Strategies. The program devotes its energies to the study of medication use, particularly among the elderly, from the disparate perspectives of pharmacology, epidemiology, clinical decision making, and health services research. In the 1980s, Avorn and colleagues pioneered studies improving physicians choice of medications through the use of educational outreach (“academic detailing”) to better inform prescribers about issues of efficacy, risk, and cost. His current research focuses on the study of adverse drug effects in the elderly through epidemiological analysis of large population-based data sets and clinical trials. Avorn’s work has been published in the Journal of the American Medical Association and The New England Journal of Medicine.
The litany of population senescence should by now be familiar to every student of geriatrics or health policy. In the United States, as in most developed countries, the proportion of people age sixty-five and over was 4 percent at the turn of the century, currently comprises 12 percent of the population, and will reach 20 percent in the next three decades. The Medicare generation consumes nearly a third of all medications, and those over age eighty-five—the group comprising the highest proportion of medically frail citizens—are the fastest-growing demographic segment in the country. Proportionately greater numbers of very old people will further intensify their disproportionate use of medications, particularly for chronic illnesses. Simultaneously, the cost of medications, which have been and remain the single most cost-effective element in the health care system, has begun to rise dramatically, outstripping even the fast-track rate of increase of the overall health care consumer price index (CPI) during the 1980s.

The economic prominence of hospital care and physician fees attracted the attention of payers, regulators, and irate consumers throughout the 1980s. Now, with a decade of quick-fix attempted solutions behind us and only limited success, attention is being drawn to targets in the health care system that are further down on the dollar-ranking scale. One of these targets is drug therapy.

Medications are of central importance in geriatric care, with the vast proportion of clinical encounters culminating in one or more prescriptions. Because drugs remain uncovered by most insurance plans for most elderly, they also loom large in the economic experience of older citizens, representing one of their highest out-of-pocket health care expenses. Much of the current and impending storm over medication costs is being driven by the mounds of photocopied pharmacy receipts mailed by retirees to their congressional representatives, along with irate cover letters decrying this most visible aspect of the high cost of health care. Pharmacologically, many elderly have less physiological reserve and greater sensitivity to the effects of drugs; similar age-related changes appear to occur for them in the political economy of health care as well.

Pharmaceuticals are an attractive target for policy intervention because of the readily identifiable drug industry. Hospitals are decentralized, often with strong community roots. Physicians, too, are decentralized; while many Americans are upset about what doctors in general do, most still think the world of their own physician. Yet few communities outside New Jersey have a corner drug company. The meretricious excesses of some companies (such as Ayerst’s “frequent prescriber bonus program,” which gave doctors free airplane tickets for putting their patients on Inderal) have begun to poison the well of public trust. Thus,
the relatively centralized and highly profitable brand-name manufacturers are prone to attract flak in the current panicky climate like a bright blip on a radar screen during a red alert. Politically, this may make some strategic sense in Washington. But it is also prudent to remember that hypervigilant gunners during the Vietnam War who shot from the hip at sudden large radar blips also took out some of our own aircraft, while the less-visible guerrillas went on to win the war.

The use of medications in the elderly patient in late twentieth-century America is a fascinating case study of the interplay of pharmacology, politics, culture, health policy, and medical practice. One might have expected that the use of the most common health care technology on the most prominent category of patient would have been a subject of overwhelming interest for some time. However, it took the enactment and subsequent repeal of the Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) to crystallize interest in this area. Like the proverbial two-by-four applied to the head of a mule, catastrophic coverage effectively caught the attention of the American public and the health care establishment. Now that the attention has been caught and the two-by-four rejected, we have a unique opportunity to think clearly about one of the most important components of our health care system for the nation’s elderly.

Alarmingly, once the spotlight of attention was focused on medications and the elderly, it revealed a landscape of black holes in the knowledge base available to address the issues at hand, ranging from an inadequate understanding of drug metabolism in the elderly all the way to questions of cost, surveillance of adverse effects, and physicians’ prescribing practices. In many instances, this was the price paid for years of failure to develop an adequate science base that would be there when needed to guide policy, whether the science was economics, epidemiology, or pharmacokinetics. In other instances, the knowledge was there but uncoupled from the policy-making process.

The elderly represent a special dimension of virtually all aspects of medication use: basic pharmacology and drug testing, prescribing and utilization, reimbursement, and postmarketing surveillance. I present a brief overview of some of the specific geriatric issues in each of these areas; several are discussed in more detail in the articles that follow in this volume of Health Affairs.

Drug Development And Regulation

As with many aspects of gerontologic research, we are only beginning to understand the richness and complexity of the scientific issues on
which geriatric pharmacology is based. Although rooted in the most arcane aspects of molecular biology, many of these physiologic questions are of immediate relevance to the millions of prescriptions being written by physicians and used by older patients each day. One clear example of this link between science, practice, and health policy is the effect of aging on drug metabolism and excretion. For many years, this was an area of little clinical interest or research importance, even though many vital medications (such as digoxin, cimetidine, lithium, and the aminoglycoside antibiotics) are cleared from the body primarily by the kidneys. In the 1970s, a cross-sectional study of subjects of all ages demonstrated a loss of approximately one-third of renal function from early adulthood through old age. In the 1980s, a follow-up paper by other investigators brought a different level of analysis to the problem. They studied subjects over time and found that, while on average their findings were similar, specific individuals had a much steeper drop, some suffered no loss of function at all, and others demonstrated the “classical” decline in renal function.

An accurate understanding of the relationship between aging and drug metabolism lies at the foundation of all clinical decision making and regulatory activity concerning geriatric drugs. Should government mandate systematic inclusion of large numbers of elderly in premarket or postmarket evaluation of drugs? Or is aging itself irrelevant, and only the existence of impaired renal or hepatic function important? How should age-related changes in receptor sensitivity relate to drug evaluation and use? Should we study normal, healthy aged or the sick elderly? Years of debate in and out of the Food and Drug Administration (FDA) over the proper role of aging in the testing and approval of new drugs make it clear that our attempts to build a rational regulatory structure in this field are limited by a meager science base. Compared to many other issues in medicine, our understanding of the basic biological issues involved in geriatric pharmacology remains surprisingly primitive.

Just as there are numerous examples of how deficits in basic geriatric pharmacologic knowledge stand in the way of making both good public policy and practicing (or defining) good medicine, equally numerous examples come from the fields of epidemiology and health services research. Several studies have shown that the number of hospitalizations for adverse drug reactions rises dramatically with increasing age, and this level of analysis has been adequate for the preparation of enormous pie charts and graphs for display and exhortation at various congressional hearings. But beneath this superficial snapshot are some interesting emperor’s-new-clothes questions that illustrate how little we actually know about this problem.
First, the elderly take more drugs than other segments of the population; this simple fact is frequently not controlled for in discussions of this issue. The distinction between changes related to aging and changes relating to disease holds endless fascination for gerontologists and might be of passing interest to policymakers and clinicians if indeed we are spending many billions of dollars and experiencing many hundreds of thousands of needless deaths annually from drug-induced illness in the elderly. The authors of one interesting study simply divided the number of adverse drug reactions experienced by patients of all ages by the number of medications that they were taking, and found that the dramatic upward spiral of adverse drug reactions with age became an unremarkable horizontal line. While there is undoubtedly more to the question than this, it illustrates how the application of long division could shed some useful light on the mechanisms of this problem.

We are not dealing here with mere academic speculation. Rather, intelligent policy and practice depend upon adequate science. For example, let us assume that a genuine increase in the risk of an adverse drug reaction does occur with normal aging. How much of the problem relates to physicians’ using these drugs suboptimally in the elderly in terms of dose, indication, and patient monitoring, even in the face of adequate data? If the physician is the problem, efforts would then best be targeted at that sector rather than at researchers, manufacturers, or regulators. Alternatively, if there simply are not enough data on adverse drug reactions in the elderly because elderly subjects are not included widely in premarketing testing, it would be unfair to expect the physician to intuit proper drug use, and pressure would best be applied to FDA and industry. Conversely, might an increased risk of adverse drug reaction be the irreducible price that must be paid for an older person to receive the benefits of the drug therapy currently available? The onus then would be on the drug development sector, rather than on practitioners or government, to generate new products that are more “gero-tolerant.” Until the relationships among these factors are understood, we will not know with much precision how to design public policy.

Inclusion of elderly in clinical trials. Two recent events will have important consequences for the “gerontization” of the drug development process. The first is the promulgation by FDA, after seven years of discussion, of guidelines for the inclusion of older patients in the premarketing trials of newly developed drugs. Paradoxically, it has long been the case that the elderly were not well represented in the premarketing studies of new medications, even for drugs (such as medications for arthritis) that would predictably be used mostly by older patients. It is too early to tell what effect the new FDA guidelines will have on the inclusion
of older subjects in such studies, in part because we still don’t know enough about which aspects of aging are most important in determining drug effectiveness or toxicity—body composition, renal function, receptor sensitivity, liver function, comorbidity, or multiple drug use. The FDA guidelines are unlikely to help with an even more difficult problem: understanding the effects of new medications in frail elderly patients with multiple chronic illnesses who are taking multiple medications. It is probably not possible or ethically defensible to require the inclusion of adequate numbers of such types of patients in premarketing trials. One solution is a more effective and systematic postmarketing surveillance of these drugs in older populations, a task discussed in more detail below.

Responsibility for the state of our knowledge base in geriatric pharmacology is not a problem that can be laid exclusively at the doorstep of the pharmaceutical industry or its regulators. One of the most glaring aspects of this lapse in science policy comes from the exclusion by large multicenter studies, often university-based, of patients older than an arbitrary cut-off point, often around age sixty to seventy. While it is often the federal government or private industry that supports these studies, one wonders about the clinical investigators who move from teaching rounds, in which hospital beds are filled primarily by elderly patients who would be the recipients of new treatments, to protocol design sessions from which such patients are systematically excluded.

The tradition of excluding elderly patients has a long history, dating back at least as far as the historic Veterans Administration cooperative trials of the 1960s, which provided clear evidence of the benefits of treating mild hypertension, but only in the nonelderly. Papers have only recently begun to appear in the literature describing the findings of large trials studying hypertension in those over age sixty-five. We must wait at least another year to learn the findings of the Systolic Hypertension in the Elderly Project (SHEP) to provide guidance to thousands of physicians and millions of their older patients on the treatment of high blood pressure in patients in their late sixties and older.

Increasingly, the misuse of medications in the elderly must be defined as including their underuse, because it has taken so long for adequate studies to be undertaken in this important area. Similar controversies surround such fundamental issues as how or even whether to use calcium or estrogen supplementation in older women to prevent hip fracture. Technologically, these studies could have been done decades ago; yet we enter the 1990s without a clear understanding of the place of these inexpensive treatments in the prevention of a devastating condition.

**Drug prices and pharmaceutical research.** The second event that will have important ripple effects on drug development for the elderly is the
ongoing study by the congressional Office of Technology Assessment (OTA) concerning the relationship between drug prices and research and development in the pharmaceutical industry. Industry representatives have long maintained that an increase in drug prices is necessary and appropriate to “plow back” a segment of the profits into the discovery of new drugs, particularly for the chronic illnesses so common in old age. However, critics have charged that a large proportion of drugs new to the U.S. market are bought rather than discovered or have their development heavily underwritten by public funding through the National Institutes of Health (NIH). According to this critique, the elderly are an important driving force behind drug development in large part because they represent a lucrative market for “me-too” drugs (such as the nth nonsteroidal anti-inflammatory agent). These products consume vast sums for development and promotional activities but finally add little that is new to the therapeutic armamentarium.\textsuperscript{13}

Regardless of the ultimate pronouncements of the OTA report, the marketplace itself will increasingly exert a disciplining effect on the drug discovery process on behalf of the elderly patient. Willingness to pay for new agents that are truly “breakthrough” drugs will certainly continue. But as more and more payers in both the private and public sector (including individuals) begin to balk at the price of costly new brand-name products that add little to less-expensive products already available, it will make less economic sense for companies to spend resources pursuing new products that amount to unremarkable also-rans. In one of those rare instances in which market forces may actually work the way they are supposed to in health care, this is likely to bring greater rigor to the targeting of drug research dollars than is currently the case.

Drug Utilization

Just as mass murders and assassination attempts periodically provoke new interest in gun control, so the abortive Medicare catastrophic coverage’s drug utilization review plan generated renewed awareness of programs to improve the use of medications in the older patient. For those who may have missed the details of this short-lived fiasco, the proposed approach was breathtakingly simple. Every prescription filled for every American over age sixty-five would be entered into a massive nationwide database (actually three databases, to bring things down to a manageable scale). To preserve the mobility and freedom of choice of the nation’s elderly, a prescription could be entered into the system from any pharmacy throughout the country or at least throughout one’s own third of the country. The computer would then scan all of the patient’s other
prescriptions and flash back to the pharmacist a warning if there were a “problem” with the prescription.

Problems so identified would be predominantly pairs of drug/drug interactions, to be specified by the Health Care Financing Administration (HCFA) later. The warning would be flashed back in abbreviated code compatible with the very limited character capacity of the small “black boxes” that each pharmacy would install. For those occasions when the megacomputer was down, there would be a toll-free number for the pharmacist (or the other tens of thousands of pharmacists in that region) to phone in the prescription.

The fantasy on which this vast system was based was that older Americans are dropping like flies because of lethal and preventable drug/drug interactions. While it is not clear where this belief came from, it is a striking example of how a concept with so little solid epidemiologic grounding could have become the foundation for an ambitious waste of national resources and people’s time. The erstwhile Medicare drug utilization review program provides evidence that it is not only physicians who occasionally rely on interventions of unproven benefit: there is virtually no rigorous evidence that this costly solution would actually have accomplished its stated goal. At least physicians try out unproven interventions on one patient at a time, after informed consent.

The massive Medicare drug utilization review system would have done little to correct one of the most important causes of medication problems in the elderly: the inadequate expertise held by most American physicians in geriatric care. The overwhelming proportion of drug-induced illness in the elderly stems from the prescribing of the wrong drug (if a drug is needed at all) or the wrong dose in an elderly patient—areas untouched by the proposed Medicare drug utilization review computer system. This problem could be addressed by mandating education or by requiring demonstration of competence in the care of the elderly as a prerequisite to receiving Medicare Part B reimbursement. Yet genuine solutions would be politically more difficult than wiring HCFA into computers in every pharmacy in America.

A preferable approach to the improvement of prescribing for the elderly would begin with the realization that it is physicians, not pharmacists, who make prescribing decisions. To make decisions that are more clinically intelligent or cost-effective, physicians need programs to teach them how to use drugs more precisely. Such programs can indeed improve medication use, even if they are funded by the federal government. Moreover, the economic benefit of such programs has been shown to exceed (by more than twofold) the cost of running them. One advantage of this approach is that it achieves its end by improving the
quality of clinical decision making and thus the quality of care.

A bill to establish a program of education in geriatric pharmacology for the nation’s physicians was drafted by Sen. John Melcher (D-MT) when he was chairman of the Senate Special Committee on Aging, but it did not survive long enough to be introduced. Modeled after other programs in physician drug education, it would have been analogous to the concept of the agricultural extension service: a systematic means of informing practicing farmers of developments in agricultural science through universities in each state. This mechanism worked well in the diffusion of agricultural technology, and many have argued that a similar approach could help to ensure that practicing physicians remain up-to-date with nonsales-oriented information about pharmacotherapy in the elderly.

In the absence of effective federal or state action on this front, this geriatric education need is beginning to be filled by other sectors, including health maintenance organizations, the Department of Veterans Affairs, and private companies. Whether in the managed care setting or in fee-for-service practice, consensus is developing that a systematic program of “educational outreach” to teach physicians about the proper use of medications is highly cost-effective and can result in more rational use of drug technologies than can be achieved by abdicating communication to drug manufacturers, who must, by definition, be concerned with product sales. Such an approach can be more effective than formulary restriction for a simple reason: choosing only one histamine, blocker or ACE inhibitor does not ensure that the agent left on the formulary is going to be used appropriately, particularly if the entire class had not been evaluated prior to the restriction. A physician education initiative was also included in legislation introduced by Senator Melcher’s successor at the Senate Special Committee on Aging, Sen. David Pryor (D-AR). However, as of this writing, it is not clear whether this component of the bill will survive the negotiations of the budget summit or be considered at a later date.

**Lack of federal agency coordination.** The inability of the various parts of the federal government to work together or with relevant parties outside government during the enactment and subsequent repeal of the Medicare catastrophic benefit was appalling. Considerable expertise was available within or through the Institute of Medicine, the National Institute on Aging, FDA, and the National Center for Health Services Research and Health Care Technology Assessment (NCHSR) on each of the issues involved in the new drug benefit, as well as from outside of government. Yet surprisingly little use was made of any of these intellectual resources. The juggernaut of program development hurtled onward
within a still-leaderless Health Care Financing Administration, with most
subtlety and reflectiveness driven out by the pressure of time and the
perception of inflexible congressional intent. Perhaps the greatest con-
tribution of the Medicare catastrophic drug utilization review experience
will be to help us learn how governmental programs can be so poorly
conceived even when enormous resources and expertise are available to
make them better.

In a confused, inchoate way, the framers and near-implementers of
drug coverage under Medicare hit on an important truth: the prescribing
of medications for the elderly is not what it should be, and we need a
mechanism to make it better. As each iteration of the projected cost of
the drug benefit emerged higher than the last, the deductible needed to
make the program economically viable also became higher. It soon
became evident that the deductible would be so high that few older
Americans would ever experience any dollar benefit from catastrophic
drug coverage. Yet the leviathan of computerized pharmacy-based drug
utilization review would be in place for all prescriptions filled for those
over age sixty-five; thus, the review process was the only “benefit” that
most older Americans would ever experience.

Ironically, the rudimentary kinds of screening that this system would
have performed have been in place in many good pharmacies for years,
and more elegant approaches are mandated in many states. Thus, the
proposed federal program would have forced pharmacies throughout
the country to install a much more primitive system than many of them
already have in place.

Drugs And Long-Term Care

If drug coverage under Medicare was the major non-event of 1990 in
the world of geriatric medication, then the time bomb of the year is surely
the implementation of the Omnibus Budget Reconciliation Act (OBRA)
regulations on drug use in nursing homes, effective 1 October 1990. The
original bill, as it worked its way through Congress, was viewed by many
as having little chance of passage, eliciting great confusion when it
became the law of the land. The sections dealing with medication use in
nursing homes were born of good intentions and concern, yet they
represent an unprecedented attempt by the federal government to man-
age individual clinical decisions. Specific medications (psychoactive
drugs) are identified along with acceptable and unacceptable indications
for their use. Armies of surveyors will comb through nursing homes to
determine whether these drugs are being used “correctly” in all cases.

Clearly, there is excessive and inappropriate use of sedating drugs in
institutional settings. Indeed, papers published in *The New England Journal of Medicine* and the *Journal of the American Medical Association* were apparently seen as key pieces of data in determining the final shape of the regulations. The regulations, uncontaminated as they are by much input from researchers in the field, cast the federal government in a role midway between police officer and insurance adjuster, a posture that has not worked well in assuring quality or containing costs over the past decade. Inevitably, we will see a dramatic improvement in paper compliance; patients in nursing homes will no longer be sedated for “crying out, yelling, or screaming” (a nonapproved indication), although the frequency of use of these same drugs will likely rise precipitously for “organic mental syndromes that cause distress” (an approved indication). We recently completed a study at the Harvard–Beth Israel Program for the Analysis of Clinical Strategies on the role of medical school–based educational outreach programs for reducing excessive psychoactive drug use in nursing homes. We were impressed with the willingness with which physicians, nurses, and aides modified their use of these drugs when presented with a coherent, relevant program of in-service education on geriatric psychopharmacology. Reduction of harmful drug use in long term care is much more likely to occur if caregivers are provided with the conceptual tools (not to mention the resources) to address patient care issues in other ways; much of this can be done even in the current reimbursement climate.

**The Study Of Drug Effects**

Pharmacoepidemiology. The epidemiologic study of drug effects offers an excellent opportunity to plug up some of the knowledge gaps that are inevitably left after a drug is approved for widespread use. In contrast to the slender representation of the elderly in premarketing trials, the elderly are disproportionately overrepresented in state Medicaid databases, which form the basis of some of the best-developed vehicles for computer-assisted, claims-based pharmacoepidemiology. Medicaid databases are also rich in complex, frail, and/or institutionalized elderly, groups who are heavy users of medication but who can never be expected to be strongly represented in routine premarket testing of drugs. In just the few years that this emerging discipline has been in place, important insights have been gained and questions raised concerning several major adverse drug effects in the elderly. Unfortunately, as with physician education, the resources available for this important task fall far short of the need, and a strong national mandate to get the work done is not evident. Yet this kind of inquiry...
provides a clear example of how small sums of research money intelligently spent could save their cost several times over in directly related public and private expenditure. A few hundred cases each year of prevented hip fracture, renal failure, or institutionalization made possible by greater understanding of adverse drug effects in the elderly would far exceed the sums currently being spent on such research nationally. Yet until a recent (if small) National Institute on Aging initiative on geriatric pharmacology, NIH has exhibited little interest in such “applied” (that is, nonmolecular) aspects of medication research, and the FDA budget to support such activities has been paltry and stagnant for over a decade. When catastrophic coverage was repealed, the HCFA Office of Research and Demonstrations notified some investigators whom it had planned to fund to study drug use in the elderly that their support had been canceled, as if the problems to be studied had been repealed with the law. Although the pharmaceutical industry now spends more annually for research than the entire NIH budget, it is probably naive to expect companies to be eager to take the lead in funding studies of drug-induced illness resulting from their products, although notable exceptions exist.

**Efficacy and toxicity.** Another category of research on nobody’s list of priorities is the study of the comparative clinical efficacy and toxicity of various drugs in the elderly. This area is not at the forefront of basic science questions, but it is at the forefront of everyday patient care questions. What is the rational physician to do when faced with a seventy-five-year-old patient with arthritic joint pain? How does the physician choose from among the many available nonsteroidal anti-inflammatory drugs, as well as aspirin or acetaminophen (Tylenol)? It might be expected that one could turn to a series of studies comparing the various drugs head-to-head in terms of the efficacy and adverse reactions of each, to come to an informed decision.

In fact, such studies are rare. FDA requires that drug manufacturers demonstrate that their new products are more effective than placebo but generally does not require detailed comparisons with existing products. Those comparisons that are supported by manufacturers may have as much input from the marketing department as from the research department; they often fail to answer the very questions that the practicing physician and patient would most like to know. Given the absence of any systematic program to develop an understanding of relative efficacy and toxicity, it is easy to understand why studies of comparative cost-effectiveness of various drugs are in even shorter supply. NIH elected to distance itself from this area in the 1970s; it is possible that the new mandate of the Agency for Health Care Policy and Research (formerly NCHSR) may impel it to pursue this agenda in the coming years if
enough interest is shown by the affected constituencies.

**Future Opportunities And Risks**

In the 1990s, the volume is being turned up on all aspects of medication use in the elderly: a larger, older, sicker population of elderly seeking medical care; new drugs on the horizon with astonishing effectiveness and equally astonishing cost; increasing involvement of payers at the state and federal level and in the private sector in the actual management of medication use; and burgeoning knowledge on the effects of old as well as new drugs on the aging body. The opportunities and risks in this arena are beginning to look exactly like those facing the physician caring for an elderly patient with multiple acute and chronic illnesses (a metaphor increasingly symbolic of the nation’s health care system): the chance to do good is enormous, the likelihood and consequences of error are large, and there is terrifyingly little room for poor judgment.

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**NOTES**