Certificate of Need and Low Capital-Cost Medical Technology

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BIOMEDICAL ADVANCES DURING THE LAST THIRTY years have spawned new medical technologies at a prodigious rate. Swift adoption of these innovations has not only altered the face of medical practice, but has transformed many hospitals into increasingly complex, resource-intensive institutions. In numerous instances, such radical change has hampered objective evaluation of clinical risks and benefits associated with these new technologies. Accompanying this trend there has been a growing concern that the costs of new equipment and procedures may be adding greatly to the inflationary trend seen in health care expenditures (Feldstein and Taylor, 1977; Altman and Wallack, 1979). One study (Abt Associates, 1975) estimated in 1975 that capital costs of major medical equipment alone may contribute 9 percent to the annual rise in hospital expenditures. Warner (1979) subsequently added operating expenses to this figure, calculating that equipment-embodied technologies alone may actually account for nearly 34 percent of the annual cost increase. One public policy response to this problem has been to attempt restraint of technology diffusion to hospitals. The prime policy instruments have been state Certificate of Need (CON) programs, which

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review and approve or reject all hospital equipment purchases involving technologies whose capital costs exceed a specified threshold or whose introduction to the hospital represents a significant change in service.

For several years now, health planners and policy makers have been concerned that some low capital-cost technologies, i.e., those falling below the established CON threshold of $150,000, may contribute more heavily to hospital cost inflation than several of their higher capital-cost counterparts. This concern is based on the impression that particular technologies requiring relatively small initial capital outlays may also generate significant operating expenses and/or other costs associated with adverse clinical consequences of their use. Under the previous administration, consideration was given to potential extension of Certificate of Need review to such presently nonreviewable technologies. Recent federal legislation (P.L. 97-35, 1981) wrought by the Reagan administration has instead raised the threshold for CON review from $150,000 to $400,000 for major medical equipment and to $250,000 for purchases involving the establishment of new institutional services. We explore here the pros and cons of this dramatic reversal in policy direction by focusing on electronic fetal monitoring as a case example. Some of the material presented here is based on a study conducted for the Bureau of Health Planning, U.S. Department of Health and Human Services, as part of a national evaluation of state Certificate of Need programs (Policy Analysis, Inc. et al., 1980).

Electronic fetal monitoring (EFM) is a diagnostic medical technology used during labor to evaluate fetal condition. It is intended to aid the obstetrician in detecting characteristic changes in the fetal heart rate which might signal possible impending fetal death or neurologic impairment. The small capital cost of EFM—roughly $8,000 to $12,000 per basic unit (depending on options selected)—has enabled it to elude scrutiny by Certificate of Need programs. Its intuitive appeal to obstetricians, coupled with its promise of perinatal benefits, have caused it to be diffused widely throughout the nation. This has occurred even though clear evidence of its net benefit does not exist, and its use is thought to be associated with changes in hospital labor requirements and operating costs, as well as with potentially costly side effects (e.g., an increase in the cesarean section rate). In the last

four years, serious questions regarding the safety, efficacy*, and cost of EFM have surfaced in the professional community (Banta and Thacker, 1979a; Hobbins et al., 1979) and in the public eye (Randal, 1978). As a consequence, health planners have become increasingly alarmed by the implications that routine use of EFM may have for the quality and cost of obstetric care.

To a large extent, the issues surrounding technology diffusion extend beyond the boundaries of a particular innovation, but the problems posed by the rapid, almost inconspicuous diffusion of EFM seem prototypical of those encountered daily by health planners and policy makers. The importance of these issues is underscored by the swiftly changing nature of the medical care "product" and by the need to constrain rising health care costs. Section I of this paper discusses some fundamental questions involving regulation of technology diffusion. Section II then examines current Certificate of Need policies regarding technology, and explores various mechanisms which may be employed in modifying existing program provisions. Section III next considers the broader question of regulation versus incentive-based solutions, and offers some suggestions for modifying behavior both within the hospital and the medical technology industry. Section IV concludes with recommended changes for health policy orientation toward technology diffusion.

I. Basic Issues in the Regulation of Technology Diffusion

The Diffusion Question

A fundamental question regarding potential extension of CON review to low capital-cost technologies is whether current diffusion levels are of serious enough concern to warrant concerted restraint. In the case of EFM, some observers would argue that the technology has diffused

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* We define *efficacy* according to the convention used by the Office of Technology Assessment (1978): "The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use."

so widely in ten years that belated regulatory intervention would likely be ineffectual and possibly meaningless at this time. These same observers might also argue that EFM is relatively inexpensive and safe, and that regulation would only introduce a layer of bureaucratic paper shuffling. On the other hand, the market for fetal monitors is undergoing change. It has now matured to the point where hospitals are making secondary and even tertiary purchases of equipment, either to augment their present capabilities or to replace older, less reliable models. In 1978, it was estimated that 20 percent of the approximately 2,000 units sold represented purchases other than first-time investments (Cohen and Cohodes, 1980). This percentage is expected to increase substantially in the next few years. In addition, it is anticipated that the total market will continue to grow, albeit at a somewhat slower pace than the present 15 to 20 percent annual rise. More important is the belief among many obstetricians that the technology itself is on the verge of significant change, and that an entirely new cycle of diffusion may occur if continuous tissue pH monitors receive Food and Drug Administration clearance to enter the marketplace. Owing to this potential for continued diffusion, critics of EFM maintain that stricter controls should be imposed (Banta and Thacker, 1979b).

Economic Considerations

The question of regulating the diffusion of EFM, or, for that matter, any medical technology, is one that requires consideration of economic, as well as noneconomic, factors. One might expect economic considerations to include, but not be limited to, such factors as: the role of medical providers in determining the number and types of services to be purchased; the effects of health insurance coverage and cost reimbursement structures on such purchasing decisions; the potential inflationary impact of service utilization on total health care costs; hospital nonprice competition; and the failure of market forces to set input and health services prices efficiently.

Of these factors, the first two apply to essentially all health services, technological or otherwise, in which the physician acts as a purchasing "agent" for the patient. This condition seems particularly relevant to EFM services where the decision to employ the equipment has principally been determined by the obstetrician, often with little acknowledgment of patient preferences. Findings from a study on

EFM use in several Massachusetts hospitals (Cohen and Cohodes, 1980) indicate that obstetricians play pivotal roles in the decision to purchase EFM equipment for their hospitals, but are likely to be influenced by departmental policies and by peer practices when employing EFM in the delivery suite. Moreover, evidence in the literature suggests that obstetricians may be relatively immune to cost considerations when making utilization decisions because service charges for EFM appear to be reimbursable by virtually every public and private health insurance carrier in the nation (Banta and Thacker, 1979b).

Economic factors also play an important role in the acquisition of EFM equipment. Next to the perceived, but undemonstrated, benefits of EFM, the most important incentive urging hospitals to invest in the technology may be the promise of significant net revenues generated from offering the service. The low capital cost of EFM is clearly not a barrier to investment; and even with considerable price variation it remains small relative to the size of a hospital's capital equipment budget, and the capital costs of other medical equipment competing for the same institutional resources (Cohen and Cohodes, 1980). It is highly unlikely that capital cost considerations alone will deter hospitals from purchasing such equipment, especially if staff obstetricians are committed to their acquisition.

The key economic criterion for regulation may involve the matter of indirect health effects and their costs. The uncertain impact of EFM on cesarean section rates has been extensively debated in the literature without clear resolution (Task Force on Cesarean Childbirth, 1980). Should the magnitude of the increase approach that estimated by Banta and Thacker (1979a), the widespread use of EFM would contribute substantially to the increase in total national health care expenditures. An economic consequence of this kind would argue for regulation of technology diffusion. If the indirect effect of EFM is found to be of much smaller magnitude, perhaps on the order of three additional cesareans per 1,000 births, as suggested from data analyzed by the Task Force on Predictors of Fetal Distress (1979), then an economic argument alone would not be sufficiently convincing.

Noneconomic Considerations

The question which remains is: If a strong case for regulation of EFM diffusion cannot be made purely on economic grounds, what other

factors might argue for it? Perhaps the reason lies in such considerations as quality of care or the effect which EFM might have on the nature of obstetric practice. In many respects, EFM would hardly be a controversial technology if concern over its risks and benefits did not exist in the medical community. As stated earlier, many practitioners have enthusiastically adopted monitoring, even though available evidence in the literature is flawed by threats to experimental validity and by disparate definitions of fetal distress used in most studies (Cohen, 1982). At present, the prevailing range of uncertainty among obstetricians is so vast that several discrepant viewpoints of EFM safety and efficacy could be articulated and defended quite reasonably (Thompson and Cohen, 1981).

Electronic fetal monitoring is also believed to have had a profound influence on the training and practice orientations of obstetricians (Cohen, 1982). For those obstetricians trained within the last decade, technology is an integral part of medical practice, and EFM is synonymous with fetal evaluation during labor. In some obstetric residency programs, EFM may be the only monitoring technique taught to young residents. For many older practitioners trained prior to 1969, the introduction of EFM clearly altered their practice habits by replacing manual techniques of evaluating fetal condition during labor. The implications of such changes in clinical practice are, as yet, unmeasured, but they suggest a potential for serious impact on the nature and quality of obstetric care. Assuming that some form of intervention (regulatory or otherwise) would be desirable from a quality assurance standpoint, the question becomes: Do Certificate of Need controls represent the most effective means of coping with the noneconomic consequences of EFM diffusion? Before addressing this question, it is important to understand the purpose of Certificate of Need programs and to define more clearly what is meant by the *diffusion* of technology.

II. Certificate of Need Regulation: Current Policies and Future Prospects

The Role of Certificate of Need Programs

Certificate of Need programs were never specifically intended to constrain the diffusion of medical technology. Historically, the primary

objective of most CON programs was (and still is) to contain capital costs associated with facility construction, renovation, replacement, conversion, and changes in service (Cohodes et al., 1978). Soon after their adoption, however, many programs began to encounter applications for new medical technology, which either exceeded the established dollar threshold for review or involved substantial changes in service (including the introduction of an entirely new service). As questions of safety, efficacy, and cost quickly arose, a few programs set out to develop technology-specific resource and utilization standards for guiding the Certificate of Need review process. Unfortunately, the development of these standards and the evolution of CON policy toward medical technology proceeded at a slow and nonuniform pace in most states (Chayet and Sonnenreich, 1978).

Contributing to this overall problem is the fact that technology diffusion may be seen to contain two distinguishable components: the *introduction* of new or innovative technology to the health care field; and the *distribution* of technology among individual health care institutions. The distinction here is important. Introduction refers to the acceptance and adoption of innovation into clinical practice, whereas distribution implies the physical allocation of equipment among institutions. Certificate of Need programs have been used in many states to attempt constraint of both elements of technology diffusion.

Findings from a study of CON experience with CT scanners (Pardini et al., 1980) suggest that CON programs have not been successful in either controlling the introduction of new technology or assuring equitable distribution of equipment among hospitals. One reason for the former problem is that CON review occurs at the time of purchase—*after* a device has been researched, developed, manufactured, and marketed. Because CON programs lack control over the development and clinical evaluation of new medical technology, their potential impact on technology adoption is greatly limited. Moreover, if the technology's capital costs are less than the specified CON threshold, it effectively eludes CON review. The latter problem—that of technology maldistribution—seems particularly acute for the municipal hospital serving a relatively sick population (Sterman and Schaumburg, 1980; Banta, 1980). Certificate of Need programs traditionally have placed greater emphasis on cost containment objectives than on other health planning goals.

A further problem is that CON review of innovative change places

health planners on less familiar (and, some would argue, inappropriate) ground, given their knowledge and skills. Since project review requires sophisticated technical, medical, and analytic skills, many CON programs find it necessary to convene panels of experts for developing meaningful application-review criteria. This process is both time-consuming and costly. It also does not ensure attainment of a desirable outcome. Newly emerging technologies present the greatest difficulty because the information and clinical data required to evaluate questions of medical safety, efficacy, and cost-effectiveness are usually not available, due to the novelty of the situation. Planners, therefore, find themselves confronted with the unpleasant dilemma of having to make important decisions with severely limited information under legislated time pressures and considerable uncertainty. However, since Certificate of Need review is the only policy mechanism available to them, at present, health planners continue to seek improved methods for analyzing hospital requests for new medical technologies (Bureau of Health Planning, 1980).

Before considering future prospects for CON review of low capital-cost technologies, it is important first to examine the strategies that are currently used to review high capital-cost technology.

Current CON Strategies Regarding High Capital-Cost Technology

Four different CON policy orientations generally have been employed by states to address the issues associated with technology proliferation (Pardini et al., 1980; Codman Research Group, 1979). While some programs hold internally consistent policy perspectives, others pursue multiple directions simultaneously, specific to particular geographic service areas or to certain types of technologies. These strategies include:

1. *Proforma denial.* This strategy emphasizes strict control over high capital-cost technology, regardless of need or efficacy. Control of costs, both capital and operating, is a major goal. This policy has been implemented in a few states for finite periods of time, usually as a result of adversarial provider-planning relations or as a consequence of high uncertainty and poor information regarding a technological

advance. In most cases, denials have resulted from serious concerns over safety, efficacy, access, and cost.

2. *Formalized strategy of delay.* The intent of this strategy is to limit technological proliferation temporarily, pending future availability of better data on need, efficacy, and methods for resource allocation. Moratoria, application review deferrals, and conditional CON decisions are all mechanisms by which difficult and/or politically sensitive proposals are delayed. The time frame for delay will vary, depending on the nature of the technology, the quantity and quality of available data, the state-of-the-art in determining need, statutory requirements for review, and the degree of provider cooperation in the state.

3. *Predetermined limits on diffusion.* This approach seeks to place limits on the level of diffusion of a given medical technology. These levels may be expressed in terms of dollar thresholds, resource limits, or utilization standards (patient procedures), and are generally based on some concept of need. This policy is more effective when providers are actively involved in determining resource limits, in setting priorities for reaching those limits, and in negotiating future goals. Tradeoffs between cost, need, and access issues are the prime concerns in programs endorsing this concept.

4. *Uncontested approval of all proposals relating to technological advances.* In this case, the CON process is a formalized approval mechanism for all technology proposals, regardless of capital cost. Little or no emphasis is placed on need, efficacy, or long-term cost implications. The goal of this strategy is to encourage technology diffusion with the intent of making diagnostic and therapeutic services universally available. Approaches of this kind develop because of political-philosophical orientation toward "free market" development, because of a strong provider presence in the planning and regulatory process, or because of a concern for equity and access to service. In some instances, this policy may be invoked for purposes of expediency, such as when CON agencies are faced with overwhelming backlogs of applications, and must concentrate their limited resources on other projects for which stringent control is most important.

For the most part, these strategies represent tactics adopted in lieu of need-based methods of project review. In addition to lacking solid methodological bases for determining "need," all four approaches appear constrained by their reliance on a high capital-cost "trigger,"

and by their inability to review technologies in the prepurchase stages of development. With these points in mind, we now examine several potential modifications to CON policy which may strengthen the program's ability to deal with low capital-cost technology.

Potential Modifications of CON Policy: Mechanisms for Reviewing Low Capital-Cost Technology

The CON policy options described here are intended primarily to constrain diffusion of low capital-cost technology. Each mechanism, however, is applicable to all technological innovations. Each must be evaluated in terms of its potential effectiveness and possible implications for economic and medical outcomes. Because the political, economic, and health care environments of each state have unique qualities, it should be borne in mind that a strategy or combination of strategies may operate effectively in one state, but may create undesirable incentives in another. Suggested options for CON program modification include:

1. *Reduce or eliminate dollar thresholds for review of capital equipment.* This option would extend CON coverage to all equipment-embodied technology by removing the high capital-cost "trigger" of most programs. A principal goal is to include those technologies which increase health care costs in the long-run through high operating and indirect costs. Justification for this action will be necessary in the form of an enlarged or redefined concept of "need." While this option might afford planners greater control over technology diffusion, it would likely produce substantial administrative costs for the program. Expanded CON coverage would not only enlarge the present burden on CON project review staff by increasing the application workload, but would require broader staff activities in criteria/standards development, project monitoring, and enforcement of CON decisions. Agency staff would also require special training and skills in the review of these technologies. Moreover, this modification would impose greater costs on providers, who would be required to seek approval for many more purchases than they do now. Before adopting such a mechanism, it would be important to evaluate whether the presumed cost savings associated with tighter control of technology diffusion outweigh the

increased administrative costs borne by both regulators and providers. Current Congressional sentiment is more likely to reduce, rather than broaden, the scope of federally mandated CON coverage.

2. *Select targeted technologies for which a Certificate of Need would be required prior to purchase and utilization.* This modification also removes the high capital-cost "trigger" of CON programs. Although it expands the present scope of coverage, it does so more selectively than the first option. It, too, requires an enlarged concept of "need" based on parameters that relate to the effects of a technology on service utilization, labor substitution, and health care costs. The selection of targeted technologies and the development of CON criteria and standards for their review both need to be conducted in cooperation with providers to ensure compliance with the program. Provider cooperation, however, has negative attributes as well; it contains the potential for provider capture or domination of the regulatory program. Thus, CON staff with specialized skills would be required under this option, and the application volume could be expected to rise; but overall, the administrative costs generated would probably be smaller than those engendered by the previous mechanism.

3. *Base CON approval, in part, on the demonstrated efficacy of the technology in question.* This modification represents a complementary strategy to either of the first two options presented here. With this policy, CON agency technical experts would evaluate proposals for new technologies not only in terms of cost, need, financial feasibility, and anticipated systemic effects, but on the basis of demonstrated efficacy as well. A satisfactory definition of efficacy, plus methods for assessing it, would need to be developed. At present, the criteria of the Medical Device Amendments of 1976 are insufficient for this purpose, since they do not define efficacy in terms of medical or health outcomes (P.L. 94-295, 1976). Provisions for development activities and for pilot clinical studies requiring lengthy lead time would also need to be incorporated into this approach. The principal advantage of requiring satisfactory evidence of safety and efficacy is that it discourages widespread marketing of an innovation until after CON approval is granted. This approach, however, may stifle development of promising innovations simply because they require either intensive or extended study to demonstrate tangible benefit. Rigorous testing of clinical efficacy through randomized controlled trials has both advantages and disadvantages. On the one hand, these trials may offer the only means

by which efficacy can be determined conclusively. On the other hand, the use of human subjects (even with informed consent) in an experimental situation poses risks which may be ethically or morally undesirable. Some observers might instead argue that it is ethically wrong to deny patients access to a potentially beneficial innovation for which preliminary evidence seems positive, but comprehensive evaluation is either inconclusive or not yet complete. The experience with EFM attests to the "double-edged" nature of this problem.

4. *Link reimbursement for services to CON approval of technology.* Open-ended, cost-based reimbursement systems provide financial incentives for technology use in the provision of services. Utilization of technology (e.g., devices or tests) is often perceived as costless by the patient due to insurance, but is actually financially rewarding to the provider. Most states with active rate-setting or prospective reimbursement programs tie reimbursement rates and hospital budgetary levels for new projects to CON approval (Hamilton, 1979). Unless projects are approved by CON, no allowance is made in the rate paid for the capital and operating costs of that project. Furthermore, the withholding of reimbursement for specific procedures not approved by CON creates financial disincentives for the unauthorized acquisition of equipment presently covered by most CON programs. Reimbursement linked to CON approval might also discourage institutions from acquiring unregulated equipment (i.e., those whose capital costs fall below CON dollar thresholds) for the financial rewards associated with their operation. This policy would function best as a joint effort by local and state CON staff with the state Medicaid agency, Blue Cross, private insurers, and Medicare carriers. When linked with any of the strategies aimed toward expanding CON coverage, this option holds relatively greater promise for constraining the diffusion of costly, new technological devices. Since it also focuses on the control of operating revenues and, thus, on the utilization of technological procedures, it may have special value in coping with low capital-cost technologies whose total costs may be inordinately large, simply by virtue of their patterns of utilization (Moloney and Rogers, 1979). Advance knowledge of how a new technology is likely to be utilized should be an important consideration in choosing among policy options.

5. *Impose statewide caps for capital expenditures, specifically for equipment purchase or lease.* By establishing an annual statewide (or areawide) limit on capital expenditures for equipment, and by evaluating all

competitive projects simultaneously, CON programs would have additional leverage to influence the diffusion of technology. Under such a policy, planners, third-party payers, and providers would negotiate a total annual statewide cap on expenditures. All proposals would then be submitted on a specified date and evaluated by a defined set of priorities and criteria. This process, termed "batching," reviews competitive applications on the basis of relative need, and is currently being considered in several states (P.L. 96-79, 1979). Tradeoffs would need to be made in such a system, but areawide and state health planning objectives would likely be enhanced. Distortions could occur, however, with priorities determined by politics rather than need.

At present, Certificate of Need programs are: 1) reactive, usually lagging well behind the market place for medical technology (Cohodes et al., 1978); 2) triggered only by large capital expenditures (Chayet and Sonnenreich, 1978); and 3) frequently blind to the relationship of capital expenditures in year t to operating expenses in year $t + n$ (Warner, 1978). The policy modifications suggested here specifically address these weaknesses. If adopted, either independently or in combination, they could, in theory, strengthen CON statutory control over technology, in general, and low capital-cost innovations, in particular. Even so, various practical limitations seem likely to intervene and to blunt CON program impact.

The Prospects for CON Control of Low Capital-Cost Technology

The preceding discussion of policy options for CON programs is based on the assumption that CON regulation of technology diffusion is both desirable and feasible. In reality, this may not be the case, as Certificate of Need, even in expanded form, may not achieve such goals. For instance, despite removal of the capital-cost "trigger" entailed by CON extension to all or selected technologies, efficiency-conscious program managers still face strong incentives to allocate proportionately greater staff resources to the review of large-capital construction projects. Consequently, many proposals for low capital-cost technologies might receive considerably less scrutiny than they deserve, especially in light of their potential impact on operating and indirect costs. Furthermore, in some states now facing sizable appli-

cation backlogs, the expected increase in application volume caused by CON program extension would clearly exacerbate the current regulatory burden (Legislative Commission on Expenditure Review, State of New York, 1977; Codman Research Group, 1979).

Other practical constraints to CON program success involve the political and economic consequences of expanded regulation. Basing CON approval, in part, on the demonstrated efficacy of the technology in question would enable CON programs to intervene much earlier and more aggressively in the premarketing stages of technology development. However, by requiring more stringent demonstration of clinical efficacy, this option would impose additional development costs on manufacturers, placing them at higher financial risk and, perhaps, inhibiting their use of venture capital. Modifications such as reimbursement linkages or statewide expenditure caps, on the other hand, are likely to elicit strong negative reaction from providers because they each restrict hospital capital investment in broader terms. Provider opposition can impede policy implementation and undermine future compliance with the program.

Finally, it must be recognized that the methodology and procedure for determining technology "needs" does not exist yet in generally accepted form. Sparse data, imperfect methods of evaluating safety and efficacy, and constantly changing technology all combine to make needs assessment extremely difficult to perform (Bureau of Health Planning, 1980). In the case of EFM, an expanded CON program might succeed in delaying further diffusion until such time when critical questions could be answered definitively, but CON review would not necessarily aid in answering those questions. Certificate of Need programs, therefore, seem to be inherently constrained in their ability to manage technology development and diffusion. Other approaches to solving these problems need to be explored.

Depending on the nature of the problem at hand, alternative regulatory strategies may hold promise in some instances. For example, if ineffective technology use by physicians is of primary concern, more rigorous utilization review procedures would be more appropriate than expanded CON review. Similarly, if the problem appears to be one of high operating costs associated with a particular technology, prospective rate setting may be a more effective regulatory instrument. Strict control of hospital charges or of allowable reimbursement levels for equipment use would produce stronger disincentives against hospital investment in questionable technology than would CON review.

The point, though, is that regulatory approaches must be compatible with the diagnosis of the problem. Because policy concerns over technology diffusion and use are multifaceted, the strategy of matching narrow regulatory programs with specific problems is inherently short-sighted. The witnessed problems (e.g., excessive or ineffective utilization) are not "problems" per se, but rather symptoms of more fundamental difficulties. The underlying problem is actually one of incentives. Cost-based reimbursement systems, the present structure of graduate medical education, and the practice of defensive medicine all create incentives for physicians and hospitals to overuse and misuse technology. Solutions which address the technology problem by recognizing the incentives that drive the diffusion process have reasonable potential for achieving more desirable outcomes. It is to these incentive-based approaches that we now turn.

III. Alternative Strategies for Coping with the Problems of Technology Diffusion

The forces that direct physicians and hospitals toward increased diffusion and use of technology are overwhelming. Media coverage of new innovations has served to heighten public expectations and to increase consumer demand. The training and socialization of today's physicians compels them to do all that they can for their patients, regardless of cost. Nonprice competition among hospitals (i.e., the "Keeping up with the Joneses" syndrome) is fostered by the reimbursement system and further stimulates demand for technology. Additional pressures are generated by proponents whose professional prominence in the medical community legitimizes their advocacy of technology adoption. Moreover, the manufacturers of medical technology are engaged in vigorous promotion of their products. These are but some of the forces that facilitate the continued growth of demand for medical technology in the 1980s (Russell, 1979; Greer, 1977; Fineberg and Hiatt, 1979; Whitted, 1981).

In the past, public controversy over social issues frequently stirred debate among regulatory advocates and free market thinkers, without satisfactory resolution. In the present discussion, it is not altogether clear whether regulation, particularly CON regulation, of medical technology is the best means for coping with technology adoption

and distribution problems. The most serious arguments raised against a regulatory approach center on the potentially adverse economic impact it is likely to produce. Rather than being merely unpalatable to technological development firms, regulation such as tying CON approval to demonstration of efficacy might seriously hinder both the creative process and the investment potential of private sector interests, posing additional problems for industry growth and for employment opportunities. Federal or state sponsored and supervised regulation might also be expected to generate substantial administrative and judicial expense. To justify its implementation, any regulatory approach whose principal goal is cost-containment should, by definition, have to produce cost savings in excess of its own administrative costs. In the case of CON extension to EFM and other low capital-cost technologies, administrative program costs have not been estimated, but recent studies (Policy Analysis, Inc. et al., 1980), coupled with the judgments of individuals presently involved in CON program administration, suggest that these costs would be formidable. Policy makers must decide, then, whether CON review of new technologies is warranted to satisfy health planning goals other than strict cost containment, such as improved access to care (Banta, 1980).

Many regulatory approaches also seem destined to commit "Type 1" errors, or what Fineberg (1979) terms "errors of underdiffusion," i.e., rejection of a needed and potentially beneficial technology for fear that it will produce adverse outcomes. This desire to avoid unfavorable outcomes serves as a barrier to market entry by new technologies that arrive on the scene with limited information available on the consequences of their use. The regulatory process is also open to diverse political pressures; CON rules and regulations in various states have reflected this (Chayet and Sonnenreich, 1978; Codman Research Group, 1979; Policy Analysis, Inc. et al., 1980). In sum, there are numerous reasons why the regulatory process has not worked well in influencing technology diffusion; and, therefore, the prospects for future regulatory success, given the nature of the process, are decidedly mixed.

Incentive-based approaches, by contrast, are appealing to some observers because they motivate technology developers and manufacturers to redirect their investment priorities without necessarily stifling the atmosphere of creative development. These approaches also focus decisions at the institutional level, reducing the government's role in everyday decisions of hospitals. In theory, they should be able to

accomplish the same goals as regulatory instruments, but without the heavy burden of a large bureaucratic apparatus.

Some Suggested Mechanisms

In view of the current concern over the limitations of regulatory strategies, a worthwhile alternative may be to speculate on potential incentive-based mechanisms. One possibility, directed specifically toward manufacturers, might be to grant exclusive marketing rights for given technologies to firms which voluntarily submit their respective products to rigorous testing. As an additional inducement, policy makers may wish to consider government subsidization of *applied* research and development activities. Having long championed the cause of basic biomedical research, often at the expense of clinical evaluation activities (Banta and Thacker, 1979b; Iglehart, 1979), federal government investment in premarket testing seems considerably overdue. Such action would serve the public interest by assuring that important safety and efficacy questions are addressed early in the technology development process. The development costs borne by the government should be offset, in the long run, by the cost savings realized through more rational diffusion and application of technology.

An entirely different approach, adopted either alone or in concert with the first, might be aimed at the institutional level. Through management incentives embodied in the hospital budgetary process, institutions could be encouraged to alter their investment strategies regarding new technology. Hospital administrators would oversee the internal process by linking departmental purchase requests for equipment with the financial performance of the requesting unit or cost center. For instance, assuming efficient operation of the department or cost center (i.e., generated revenues exceed the costs of service provision), the unit would be permitted to invest its surplus revenue in equipment-embodied technology of its choosing, provided that: available evidence indicates the device meets "satisfactory" standards of safety and efficacy; and the purchase is consistent with institutional service objectives and management priorities. Under this strategy, individual operating units are rewarded for efficient performance with new or additional acquisitions, and hospitals are recompensed for their efforts with favorable reimbursement rates. The principal advantages of this incentive-based approach are that: capital investment in technology is based on performance of individual cost centers; hospital-

wide efficiency and cost containment objectives are encouraged; and managerial discretion regarding technology acquisition remains largely with the hospital.

A third alternative—one involving the use of hospital reimbursement incentives—would require the presence and cooperation of a rate-setting authority. Under this scheme, hospitals would be paid a fixed dollar amount per case or per diagnosis (i.e., the case-mix approach). If the hospital is efficient, it may keep the difference between its actual costs and the amount reimbursed, and may invest this sum in whatever way its administrators desire, including the purchase of technology that may enhance the quality and/or cost-effectiveness of its services.

Another alternative would require the development of technology-sensitive fee schedules for physicians. In this approach, federal or state physician fee schedules would be developed whereby the participating physician would accept the established fee per procedure as full payment. In establishing the fee schedules, the pricing system for physician services would be structured so as to make it less profitable for the physician to use overly expensive or marginally useful technology when suitable lower cost alternatives are available (Gaus and Cooper, 1979).

Other strategies that might be considered include: the creation of centralized laboratory facilities for handling testing for a number of community hospitals with computer tie-ins to the laboratory for immediate feedback; changes in the residency training programs of young physicians; continuing education programs for practicing physicians; and consumer education programs.

There is, of course, no guarantee that such incentive-based methods will succeed where regulatory strategies appear to have failed. Careful consideration must be given to the potential shortcomings of any new approach, but in view of our need to deal more effectively with technological change in the health care system, innovative incentive-based approaches may be just what the doctor must order.

IV. Conclusions

In their present state, Certificate of Need programs are structurally constrained in their efforts to control technology diffusion (Pardini

et al., 1980). Expansion of the regulatory scope of CON programs would not necessarily overcome these constraints, and it is our belief that serious new problems would arise to limit program effectiveness. Even so, the opposing policy of program contraction, such as that embodied in recent health-planning legislation, may prove no better since the fundamental issue of competing regulatory objectives (cost-containment versus improved-access) is not squarely addressed.

Regulation was originally introduced into the marketplace for medical technology because the market failed to consider all of the costs and benefits associated with a new innovation. This approach, however, sought to substitute bureaucratic judgment for the deficiencies of the marketplace. As a consequence, it opened itself up to the same dangers of inefficiency and misallocation. In instances where cost-effectiveness assumes precedence over other concerns, the most important criterion for determining the desirability of regulatory intervention should be whether the total costs averted through restraint of technology diffusion exceed the anticipated costs of such regulation. When other factors are of equally valid or greater concern to society, this criterion may not suffice. In either case, further exploration and appraisal of policy alternatives (incentive-based structures as well as regulatory solutions) is clearly needed.

We recommend, therefore, that policy makers address themselves to the formulation of policies regarding the development and evaluation of medical technology, and specifically to the creation of mechanisms which: are more timely in their response to innovation, and are targeted toward *total* costs of technology rather than capital costs alone. We further recommend that new policies focus on the underlying incentive problems rather than on the symptoms, with special attention devoted to understanding the forces that spur the demand for and use of medical technology.

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