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## CHANGES IN THE PUBLIC'S HEALTH AND REGULATORY NEEDS

By Stephen P. Teret\*
AND JAMES R. MILLER\*\*

The health status of a population, including its morbidity and mortality statistics, is generally discussed in journals of public health. It is unusual for such matters to be found in a law journal, even though a clear relationship exists between laws governing peoples' behaviors and the effects of those behaviors on the public's health. Much of law is directed toward individuals as opposed to populations, and court made law proceeds on an anecdotal basis, employing single case histories as precedent. Public health, on the other hand, examines disease and injury burdens on large populations, with epidemiology and biostatistics as its tools for determining what is significant.

Robert Clark's article, Why Does Health Care Regulation Fail?\footnote{1} raises important public health issues and is primarily concerned with the law's opportunity to regulate the medical profession. The author provides provocative suggestions as to how this can be effectively done. In this commentary, however, we choose not to discuss Clark's examples of legal deference to physicians or his suggestions for regulatory reform; instead we will examine the initial presumptions regarding health status and health care costs upon which he grounds his arguments. While we may agree with some of Clark's ultimate recommendations (e.g., increasing lay control of institutions and regulatory agencies; expanding lay health education; and enabling a wider range of activity for non-physician health care workers), it is essential to analyze critically his initial presumptions.

Clark's article decries the deference law has paid to the medical profession — a legal deference manifested by inadequate and ineffective regulation. Assuming the accuracy of Clark's observation, one is tempted to demur: so what if the medical profession is not strictly regulated, particularly in our anti-regulatory, political climate? Clark's re-

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<sup>1. 41</sup> MD. L. REV. 1 (1981)

sponse, and the notion upon which his thesis is grounded, is that this deference has led us to spend more on health care for less benefit.

True, as Clark points out, the percentage of the gross national product that we devote to expenditures on medical care continues to increase. True, crude mortality rates have decreased only modestly in the last two decades. But these statements are too broad to permit one to draw from them the inference that we are not getting our money's worth. What elements of health care costs have most significantly contributed to the rise? How have disease specific mortality rates changed during this period? Have the mortality rates for certain segments of the population changed while others remained the same? The answers to questions such as these permit a more accurate understanding of the public's health, the health care delivery system, and the benefits our health care dollars have bought.

Clark tells us that in the past two decades death rates in the American population have changed only slightly, representing "the merest blip on the graph." This is not wholly accurate.

Death rates generally measure the number of deaths that occur in a population during a given period of time, i.e.:

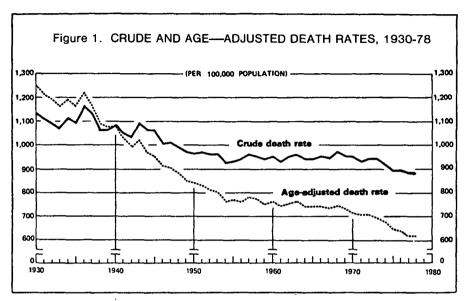
Annual crude death rate from all causes per 1,000 population = Total number of deaths during year Number of persons in population at mid year × 1,000

Crude death rates, however, have the potential for masking changes that are occurring in the mortality patterns of a population. Death rates differ for the various age groups in a population, with the older age groups generally having higher age-specific death rates than the younger age groups. Thus, if a population ages (i.e., if the average age of the population increases), there will be more people in the higher age-specific death rate groups and the crude death rate of the entire population will therefore not show decreases.

But, in computing mortality rates, adjustments can be made that will correct for this potentially misleading phenomenon. An age-adjusted death rate shows what mortality levels would be if there were no changes in the age composition of a population from year to year.

Figure 1 shows both the crude death rates and age-adjusted death rates for the United States from 1930 to 1978. The age-adjusted death rate is a more realistic indicator of changes in the risk of dying over a period of years. In 1961, the age-adjusted death rate for the United States was 735.6/100,000; in 1978 it was 606.1/100,000, a decrease of

17.6%.<sup>2</sup> The 1978 age-adjusted death rate is the lowest level ever recorded in the United States. It has greater significance than a mere "blip on a graph."



Source: National Center for Health Statistics, U.S. Dep't of Health & Human Services, Public Health Service No. 80-1120, Monthly Vital Statistics Report: Final Monthly Statistics, 1978, at 1 (1980).

It is instructive to examine not only the changes in total death rates over time, but also how the disease-specific composition of these death rates has changed. If attention is focused only on total death rates, major changes in death rates for specific diseases may cancel each other out and thereby go unnoticed. For example, death rates from cervical cancer have shown substantial change. In 1960, the United States death rate for this disease was 15.8 per 100,000 non-white women and 8.5 per 100,000 white women.<sup>3</sup> By 1976, these rates dropped to 8.4 and 4.5 per 100,000 non-white and white women respectively.<sup>4</sup>

The diseases which most seriously affected our population in the first half of this century were infectious diseases. The battles waged by

<sup>2.</sup> NATIONAL CENTER FOR HEALTH STATISTICS, U.S. DEP'T OF HEALTH & HUMAN SERVICES, PUBLIC HEALTH SERVICE NO. 80–1120, MONTHLY VITAL STATISTICS REPORT: FINAL MORTALITY STATISTICS, 1978, at 17 (1980).

<sup>3.</sup> U.S. Dep't of Health, Education & Welfare, Vital Statistics of the United States 1960, at 5-18 (1963).

<sup>4.</sup> U.S. DEP'T OF HEALTH & HUMAN SERVICES, VITAL STATISTICS OF THE UNITED STATES 1976, at 1-102 (1980).

health workers during this period were to identify the pathogens which caused the diseases and then somehow to remove those pathogens from the environment or to immunize the population from their effects. Successes were accomplished through measures such as:

- immunization programs for diphtheria;
- improvements in milk and water quality which reduced the incidence of diarrheal diseases;
- smallpox vaccination, which eventually eradicated that disease; and
- effective treatment of tuberculosis through antibacterial drugs.

In the second half of this century, the availability of vaccines greatly reduced the incidence of certain serious childhood diseases, as shown by Figure 2.

Figure 2. DEATH RATES (PER 100,000) FOR LEADING CAUSES OF DEATH, UNITED STATES, 1900 AND 1975

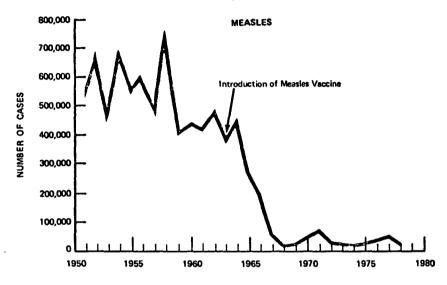
	1900				
	Rank and Cause of Death	Rate	Percent of All Deaths		
1	Pneumonia and influenza	202.2	11.8		
2	Tuberculosis (all forms)	194.4	11.3		
3	Diarrhea, enteritis, ulceration of intestine	142.7	8.3		
4	Diseases of heart	137.4	8.0		
5	Intracranial lesions of vascular origin	106.9	6.2		
6	Nephritis	81.0	4.7		
7	All accidents	72.3	4.2		
8	Malignant neoplasms (cancer)	64.0	3.7		
9	Certain diseases of early infancy	62.6	3.6		
10	Diphtheria	40.3	2.3		
	All causes	1719.1	100.0		

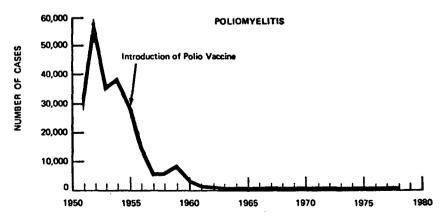
	1975		
	Rank and Cause of Death	Rate	Percent of All Deaths
1	Diseases of heart	336.2	37.8
2	Malignant neoplasms (cancer)	171.7	19.3
3	Cerebrovascular disease	91.1	10.3
4	Accidents	48.4	5.4
5	Influenza, pneumonia	26.1	2.9
6	Diabetes mellitus	16.5	1.9
7	Cirrhosis of liver	14.8	1.7
8	Arteriosclerosis	13.6	1.5
9	Suicide	12.7	1.4
10	Certain causes of mortality in early infancy All causes	12.5 888.5	1.4 100.0

Source: U.S. Dep't of Health, Education & Welfare, Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention 94 (1979).

But the lives which were saved from the effects of these infectious diseases became lives which were at risk for the chronic diseases. By 1975, heart disease, cancer and stroke had replaced pneumonia, tuberculosis and diarrhea as our top killers. Figure 3 compares the leading causes of death in the United States for 1900 and 1975. Heart disease

Figure 3. REPORTED CASES OF MEASLES AND POLIOMYLETIS: UNITED STATES, 1951-1978





Source: Lilienfeld, "Chronic Diseases," in Public Health and Preventive Medicine 1136 (J. Last, ed., Appleton-Century-Crofts, 1980).

and cancer, the two leading causes of death in 1975, then accounted for 57.1% of all deaths, but in 1900 the same two diseases accounted for

only 11.7% of all deaths.5

The present leading causes of death are not susceptible to the same types of drug therapy or prevention which were effective in combating infectious diseases. These new killers involve the environment, manmade products and behavioral patterns. It is estimated that in the United States in 1981 there will be approximately 800,000 new cases of cancer.<sup>6</sup> We have convincing epidemiologic data to associate some of these cancers with exposures to carcinogens such as cigarette smoke,<sup>7</sup> ionizing radiation,<sup>8</sup> occupational exposures to materials like asbestos<sup>9</sup> and vinyl chloride,<sup>10</sup> and prenatal exposure to synthetic estrogens (e.g., diethylstilbestrol, or DES).<sup>11</sup> Eliminating these types of exposures can be costly and difficult.

For example, it is known that there is an association between benzene exposure and leukemia.<sup>12</sup> More than one million workers in the United States are exposed to benzene at their worksites.<sup>13</sup> In an effort to regulate the amount of some of these exposures, the Occupational Safety and Health Administration (OSHA) promulgated a standard which, in part, reduced the permissible exposure levels in the workplace atmosphere from 10 parts per million to 1 part per million.<sup>14</sup> The estimated cost for industry to comply with the regulation was \$0.5 billion. The Supreme Court, in *Industrial Union Department v. American Petroleum Institute*, <sup>15</sup> overturned the standard, reasoning that it was not adequately supported by scientific findings.

Injuries are the leading cause of death in the United States for persons between the ages of one and forty. About 29 million bed days in short-stay hospitals are required each year for treatment of the in-

<sup>5.</sup> Lilienfeld, *Chronic Diseases*, in Public Health and Preventive Medicine 1136 (J. Last ed. 1980).

<sup>6.</sup> American Cancer Society, Cancer 1981 Facts and Figures 1 (1981).

<sup>7.</sup> U.S. Dep't of Health, Education & Welfare, Smoking and Health, A Report of the Surgeon General (1979).

<sup>8.</sup> Lewis, Leukemia and Ionizing Radiation, 125 Science 965 (1957).

<sup>9.</sup> Selikoff, Chung & Hammond, Asbestos Exposure and Neoplasia, 188 J.A.M.A. 22 (1964).

<sup>10.</sup> Creech & Johnson, Angiosarcoma of Liver in the Manufacture of Polyvinyl Chloride, 16 J. Occup. Med. 150 (1974).

<sup>11.</sup> Herbst, Ulfelder & Poskanzer, Adenocarcinoma of the Vagina; Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women, 284 New Eng. J. Med. 878 (1971).

<sup>12.</sup> Infante, Rinsky, Wagoner & Young, Leukemia in Benzene Workers, 2 LANCET 76 (1977).

<sup>13.</sup> Industrial Union Dep't v. American Petroleum Inst., 100 S. Ct. 2844, 2851 (1980).

<sup>14.</sup> OSHA, Benzene, 29 C.F.R. § 1910.1028 (1980).

<sup>15. 100</sup> S. Ct. 2844 (1980).

jured.<sup>16</sup> In terms of cost to society, motor vehicle injuries rank second only to cancer, and exceed the cost of coronary heart disease.<sup>17</sup> The technology for preventing thousands of motor vehicle deaths by the use of air bags has been developed for years, but it is still not possible for the consumer to purchase a car equipped with air bags, due to the manufacturers' steadfast refusal to install them and government's refusal to mandate them.<sup>18</sup>

Given the fact that reductions in most of the current leading causes of death involve environmental and behavioral modifications, regulation of the medical profession does not appear to be a fruitful approach to reducing these death rates.

Some of our regulations provide for the costliest type of medical care. The 1972 amendments to the Social Security Act provide Medicare coverage for every individual who "is medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease. . . ." As a result of this legislation, the End Stage Renal Disease (ESRD) Program was developed by the government to reimburse physicians and facilities providing care to these patients.

The ESRD Program began on July 1, 1973 with approximately 11,000 patients. By 1979, the enrollment was 56,000 patients, and the estimated cost for the program in 1979 was \$1.2 billion.<sup>20</sup> But for this staggering cost, we have bought the lives of the 56,000 participants, because before the techniques of renal dialysis were developed in the 1960's, these patients would not have survived their kidney disease. The expenses incurred for the care of these persons were authorized by Congress, as a matter of policy; they were not created by the medical profession as a result of inadequate regulation. The medical profession did advance its state of the art by devising a way to prolong the lives of those with kidney disease, and the country decided to purchase that care.

<sup>16.</sup> Haddon & Baker, *Injury Control*, in Preventive and Community Medicine 109 (2d ed. D. Clark & B. MacMahon 1981).

<sup>17.</sup> Hartunian, Smart & Thompson, The Incidence and Economic Costs of Cancer, Motor Vehicle Injuries, Coronary Heart Disease, and Stroke: A Comparative Analysis, 70 AM. J. Pub. Health 1249 (1980).

<sup>18.</sup> On October 29, 1981, the United States Department of Transportation rescinded that portion of Federal Motor Vehicle Safety Standard 208 which would have required that all cars sold in this country be equipped with passive restraint systems. 46 Fed. Reg. 53419 (1981) (to be codified in 49 C.F.R. § 571).

<sup>19.</sup> Social Security Amendments of 1972, Pub. L. No. 92-603, § 2991, 86 Stat. 1463.

<sup>20.</sup> U.S. Dep't of Health & Human Services, Health Care Financing Grants and Contracts Reports, Implementing the End-Stage Renal Disease Program of Medicare vii (1981).

Advances in medical science, therefore, incur substantial expenses that sometimes continue far beyond the point of initial treatment. We learn how to provide heroic medical measures to increase the survival rate of medical catastrophes and then place the survivors in long-term nursing care facilities at enormous daily expenses. A recent article by Luginbuhl et al. on cost containment provides the following example:

The increase in health costs as a percentage of the gross national product is particularly disturbing since it indicates that "investment" in health care may not return its cost in increased productivity. This phenomenon is understandable if one considers the nature of most illness today, and if one includes in the analysis the impact of both future earnings and expenses in addition to direct expenditures for health care. A comparison of two different illnesses can serve to illustrate these principles.

A thirty-year-old man treated for lobar pneumonia with penicillin in 1950 recovers and continues working for the next thirty-five years. His total earnings can be expected to more than offset his total expenses, including medical care costs. There is a net gain as a result of the treatment. If this same individual is treated for myocardial infarction at age sixty-five, he will probably not return to work following his recovery. For the remainder of his life he will continue to consume goods and services, including medical care, but will not contribute to production. If our total national expenditure for health care is increasingly composed of episodes of the latter type rather than the former, then rising costs seem inevitable.<sup>21</sup>

The cost of health care, without question, has dramatically increased over the past two decades. But, to equate the increasing cost of health care with an increasing cost of physicians would be in error. Health care costs, as traditionally computed, include not only physician fees but hospital costs, drugs, dental care, nursing home care, research, etc. Hospital costs may be broken down further to indicate the costs of equipment, building, medical staff salaries and supporting staff salaries.

The relative sizes of the costs of these health care components change over time. For example, in 1950 nursing home care accounted for 1.5% of all health care costs, whereas in 1973 it accounted for 7.1% of such costs. On the other hand, physicians' services dropped from 21.7% to 18.4% of total health care costs between 1950 and 1973.<sup>22</sup> The

<sup>21.</sup> Luginbuhl, Forsyth, Hirsch & Goodman, Prevention and Rehabilitation as a Means of Cost Containment: The Example of Myocardial Infarction, 2 J. Pub. Health Pol'y 103, 103 (1981).

<sup>22.</sup> Breslow, *Personal Health Care*, in Public Health and Preventive Medicine 1749 (J. Last ed. 1980).

increase in nursing home care costs reflects the aging of our population as previously discussed. Between 1963 and 1976 the number of nursing home beds has nearly tripled, increasing from 568,560 to 1,406,778.<sup>23</sup>

The general increase of our health care costs as a percentage of our GNP is an important phenomenon that calls for careful examination. It is necessary to dissect these costs to determine what has driven them up. Figure 4 illustrates how the various components of health care

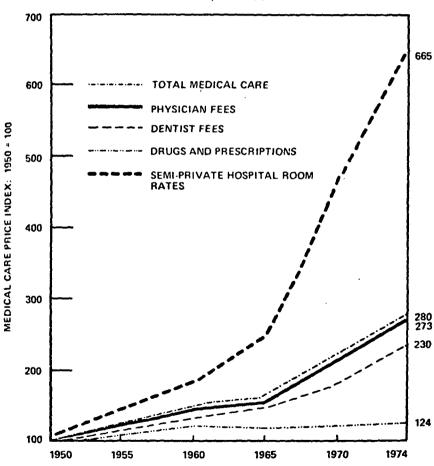


Figure 4. THE INCREASING COSTS OF MEDICAL CARE U.S.A., 1950-1974

Source: Rogers, "The Challenge of Primary Care," in Doing Better and Feeling Worse 89 (John Knowles, ed., W.W. Norton & Co., Inc., 1977).

<sup>23.</sup> AMERICAN MEDICAL ASSOCIATION, SOCIOECONOMIC ISSUES OF HEALTH, 1980, at 167 (1980).

costs have increased between 1950 and 1974.<sup>24</sup> It is clear from this chart that the hospital room rate component is the one which has skyrocketed.

One of the chief factors contributing to the dramatic rise in hospital room costs in the mid-sixties was the increase in hospital worker salaries. Hospital workers were often from minority groups and had long been paid at rates lower than other private, non-agricultural employees. Coinciding with the civil rights movement in the 1960's and with the growing number of hospitals having collective bargaining agreements, the "[w]ages of hospital workers increased at a rate almost double that of workers in other industries in the period 1966-1969."25 This "catching up" in wages was of great social importance, but could be expected to produce little or no change in mortality statistics of health care recipients.

Herbert Klarman, a health economist, has recently analyzed increasing hospital costs in the following manner:

For short-term hospitals, . . . between 1966 and 1976, the increase in utilization accounted for 16 percent of the increase in expenditures, and the increase in patient-day cost (adjusted for the change in the volume of ambulatory care) accounted for 84 percent . . . . As for unit cost, increases in factor inputs or intensity, such as staffing and supplies, accounted for one-third, and increases in prices, including wages and fringe benefits, accounted for two-thirds of the increase in adjusted patient-day cost.<sup>26</sup>

Also greatly contributing to the increase in health care costs was the movement to give disadvantaged groups greater access to health care. Any chart on health care costs takes a marked upturn in the mid-60's with the introduction of Medicare and Medicaid. These programs have reduced the gap of health care services between groups in our society, but only at great cost.

A recent study by Davis et al. on access to health care for the poor finds that important progress has been bought by these programs:

Major strides have been made by the poor in use of physician services. In 1964 the poor visited physicians less frequently than the nonpoor, even though they experienced a greater incidence of acute and chronic health conditions. By 1978, this pattern was re-

<sup>24.</sup> See Rogers, The Challenge of Primary Care, in Doing Better and Feeling Worse (J. Knowles ed. 1977).

<sup>25.</sup> A. SORKIN, HEALTH MANPOWER 12 (1977).

<sup>26.</sup> Klarman, Health Care Financing, in Preventive and Community Medicine 162 (2d ed. D. Clark & B. MacMahon 1981).

versed and the poor slightly exceeded the nonpoor in the use of physician services.<sup>27</sup>

The important points of all the foregoing data are that the composition of our population, its causes of death, and its access to health care have been changing dramatically. To assert that we now spend too much on health care for inadequate benefits, and that this situation can be reversed by regulating physicians, is a facile but false proposition. If the goal is to enhance the public's health (rather than to exercise a stricter legal dominion over medicine), we must then understand our health status and its current components.

Law can cause lives to be saved. For example, Robertson recently reported his findings that, due directly to the Federal Motor Vehicle Safety Standards,<sup>28</sup> 37,000 fewer deaths occurred in the United States between 1975 and 1978.<sup>29</sup> OSHA's cotton dust workplace standard,<sup>30</sup> recently upheld by the United States Supreme Court,<sup>31</sup> is expected to reduce substantially the incidence of byssinosis or "brown lung" disease among textile workers. Laws and regulations such as these, which primarily protect us from our own, man-made products, have the greatest likelihood of enhancing our health.

<sup>27.</sup> Davis, Gold & Makuc, Access to Health Care for the Poor: Does the Gap Remain? 2 Ann. Rev. Pub. Health 159, 179 (1981).

<sup>28.</sup> FEDERAL MOTOR VEHICLE SAFETY STANDARDS, 49 C.F.R. § 571 (1980).

<sup>29.</sup> Robertson, Automobile Safety Regulations and Death Reductions in the United States, 71 Am. J. Pub. Health 818 (1981).

<sup>30.</sup> OSHA, Cotton Dust, 29 C.F.R. § 1910.1043 (1980).

<sup>31.</sup> American Textile Mfrs. Inst. v. Donovan, 101 S. Ct. 2478 (1981).