The Sovietization of American Medicine: Notes from the Front Lines

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Introduction

After the demise of the Soviet Union, former Soviet citizens are able, like patients suffering from allergic disorders, to detect in their present conditions the circumstances that remind them of their experience in the Soviet Union.¹

As one of these "survivors" who is now an academic physician in New York, I am sensitive to those features of today's medicine in the United States that are heavily reminiscent of the life "back in the USSR" and that I describe collectively using the term "Sovietization." This term refers primarily to the ever-increasing levels of bureaucratization and propaganda that, as I will attempt to show, threaten the integrity of American medicine.

A Brief History

The Soviets were the councils that served as an administrative arm of the Bolshevik government after the October revolution of 1917. They were staffed by the party "apparatchiks," who had little understanding of the areas that they were administering. Rather than focusing on the real issues at hand—healthcare, education, industry, culture, etc.—they engaged in developing an enormous, politically motivated bureaucracy, which produced an inordinate amount of mandatory paperwork, rules, regulations, and plans (including the infamous 7-year and 5-year plans.) The plans were always fulfilled and the regulations were always followed on paper, while in reality the economy was collapsing. Soviet citizens were, of course, fully aware of the discrepancy between the government-fed propaganda and the real state of affairs. The enormous gap between the "rulers" ("them") and the people ("us") was reflected in endless jokes and proverbs, for example: "They pretend that they pay us and we pretend that we work."

In response to the skepticism of the populace about the truthfulness of the propaganda, the government encouraged the use of military terminology, even in the description of peaceful endeavors, so that any dissent could be viewed as if it were treason at a time of war. In an interesting analogy, writings about today's American medicine commonly make use of military terms. For example, a recent article in the *New England Journal of Medicine* about a successful primary-care practice carried the subtitle "Lessons from the Trenches."

Whom or what is American medicine fighting? I think that physicians and other "healthcare providers" are fighting against an avalanche of useless and harmful bureaucracy and regulation that devours large portions of our time and is disconnected from the real concerns of physicians and their patients. Terms like "healthcare provider," "clients," and "consumers" are used increasingly, eviscerating the notions of the fiduciary

responsibility and of the feeling of trust that historically characterized patient-physician relationships.⁵

Modern American medicine is engaged in many activities, including the primary functions of patient care, medical education, and research. In the last decade, these activities have increasingly gravitated toward hospitals' control. More than half of all physician practices in the U.S. are now owned by hospitals, including large teaching hospitals, often called "medical centers," which are commonly affiliated with medical schools.

Hospitals are subject to regulation by multiple bureaucratic organizations. For example, the teaching hospital in which I work is subject to regulation by the New York State Department of Health, the Joint Commission, the Accreditation Council for Graduate Medical Education (ACGME), the Center for Medicare and Medicaid Services (CMS), and so on.

In addition, hospital budgets are critically influenced by state budgets (for Medicaid patients), the federal budget (Medicare and Medicaid), and multiple private insurance companies, each with its own set of rules and requirements. To comply with regulators, a hospital develops its own bureaucratic apparatus, including evergrowing administration, and departments responsible for "quality of care" and "utilization review."

Since it would be impossible here to analyze in detail all the bureaucratic regulations that have been introduced into today's practice of medicine in the U.S. and to demonstrate their mostly useless nature, I will focus on just two of the regulatory trends: those guiding clinical practice, including "quality and safety" programs in hospitals, promulgated by the Joint Commission and other government and quasi-government agencies; and those guiding postgraduate medical education, promulgated by ACGME. I will also briefly address the current trend for forceful introduction of electronic medical records. But before I get to these specific examples, just a few words about what is usually presented as the "root cause" of regulatory bureaucracy everywhere: proverbial "good intentions."

The idea of Communism, of course, is one of the grandest "good intentions": the organs of production are owned collectively, everyone contributes to the common good "according to his or her means," and everyone receives "according to his or her needs." Multiple problems of capitalism, such as inequality, exploitation, periodic economic crises, unemployment, etc., are resolved, and the full-of-contradictions capitalist society is replaced by a harmonious Communist one.

What inevitably happens instead, as proven by multiple attempts to construct such a society not only in the former Soviet Union but also in Eastern Europe, China, Cambodia, Vietnam, and Cuba, is tyranny, millions of lost lives, and economic collapse. But once again, the initial intent was nothing but good. Indeed, "all

tyrannies involve the supposedly perfect understanding of someone else's needs."

As with the supposed goals of a Communist society, bureaucratic regulatory interventions in all aspects of American medicine have seemingly commendable goals⁸—primarily, improvement of both "safety" and "quality" of medical care.

The Safety and Quality Movements

The movement for improvement of safety in medicine owes its existence to medical errors. It is proposed that by introducing a variety of rules and regulations, these errors can be eliminated.

The movement is fueled, at least in part, by the Institute of Medicine's report issued in 1999.9 The report, To Err is Human, estimated that there were between 44,000 and 98,000 deaths from medical errors annually in U.S. hospitals. The report characterizes itself as a "consensus report"—a type of scientific article that is considered to possess the lowest level of evidence.¹⁰ It is easy to see how inaccurate this report must be, because its estimate of the deaths from medical errors contains within itself an error of more than 100 percent (a range from 44,000 to 98,000). Furthermore, one needs only to recall the accuracy of other government estimates to realize how erroneous such estimates can be. For example, in 1997 government "experts" predicted a surplus of physicians. The falsity of that prediction was obvious because of the many factors that continue to drive the need for medical services, including, for example, significant growth of the elderly population in the U.S., increasing complexity of cases, new medical technology, and others. 11 As of now, not only is there a shortage of primary-care physicians, but also a continuing shortage of specialists.12

Further, because the body of medical knowledge is expanding rapidly, it has become impossible for a single physician to know enough of "all medicine" to provide modern medical care. Even very common conditions, such as coronary artery disease, diabetes, hypertension, and cancer, in many cases require the sophisticated knowledge of medical specialists. This is well understood by young physicians and even by first-year medical students, ¹³ most of whom are planning to specialize.

Another example of an expert government prediction that failed spectacularly was the idea that the introduction of Health Maintenance Organizations (HMOs), with their "gate-keepers," requirement for referrals, and "capitated" reimbursement schemes would control rising healthcare costs. We all know what happened with this prediction, and not just in the U.S. ¹⁴ Similarly, a recent example of the government's inability to predict accurately is the effort by the government to determine the cost of so-called Accountable Care Organizations. ¹⁵⁻¹⁹ Of course, the most impressive examples of government failure to predict complex processes accurately were the aforementioned 7-year and 5-year Soviet economic plans.

In spite of the faulty nature of the report on medical errors, the Joint Commission has issued 70 manuals, each containing 500 pages or more of regulations and guidelines, in an attempt to eliminate medical errors and to improve safety of care. These regulations appear to be based on "common sense," but, except for

infection control measures, there is no definitive evidence that implementing any of them results in improved patient outcomes.²⁰

That "common sense" can lead one astray is, of course, common knowledge. For example, "rapid response teams," which were introduced to improve outcomes in patients whose condition is rapidly deteriorating, have not been shown to improve patient outcomes.²¹ Large studies of Medicare programs failed to produce any evidence of benefits, whether they used "pay for performance" or any other approaches to improve patient safety and quality of medical care. ^{18, 19, 22-25}

The "Quality-of-Care" movement is a prominent Soviet-style feature of today's American medicine. Like the "safety movement," this movement is based on the false assumption that the quality of medical care in the U.S. is poor. This assumption is allegedly supported by some statistical measures, for example, by such commonly cited indicators as the U.S. infant mortality (No. 34 in the world) or life expectancy (No. 37 in the world.)²⁶ It is well known, however, that these are measures of population health rather than of the medical system performance, and are influenced heavily by a variety of socioeconomic factors, such as levels of poverty or even mortgage default rates. 27-29 Also, it is not so well known that the U.S. defines a live infant birth as the expulsion of a product of conception at any stage of gestation, any weight, any length, which shows any sign of respiration, any pulsation of the umbilical cord, or any spontaneous muscular movement. Some other nations do not count a birth as the birth of a live infant unless a certain stage of gestation, or a certain weight or length has been attained, or even unless the infant lives for at least 3 days. Therefore, the U.S. infant mortality rate is likely better than No. 34 in the world, despite our diverse population.

The Joint Commission itself provides evidence that its own "quality" measures are useless. On Sept 12, 2011, the Joint Commission published a list of 405 hospitals that perform best by Joint Commission indicators. None of the best hospitals in the country, including Massachusetts General Hospital in Boston, Mayo Clinic in Rochester, Minn., Johns Hopkins in Baltimore, or any other hospital on the 17 best U.S. hospitals list compiled by *U.S. News and World Report* for its "Best Hospitals Honor Roll" ended up on the Joint Commission's "best hospital" list.³⁰ Although Dr. Mark R. Chassin, president of the Joint Commission, attempted to defend his list of measures by saying that "reputation and performance...do not always correlate," the inevitable conclusion is that it is not hospitals that are a problem, but the Joint Commission's indicators and other commonly used measures to judge hospitals.³¹

Despite unresolved problems with the accuracy of measures of the quality of care, ³² Joint Commission regulations mandate that "quality improvement" protocols be implemented in every hospital or medical center. These protocols commonly involve "measuring" either "outcomes" or "processes of care" (for example, the number of times blood pressure is taken during clinic visits—a "process measure"—and the number of times the patient's blood pressure actually meets required "standards"—an outcome measure).

Although, once again, well intended, these efforts at tracking various measures and developing plans for their improvement have no scientific or practical basis, and when they are examined rigorously, often prove to be useless.^{25,33,34}

The unsubstantiated "safety" and "quality" requirements interfere with the work of physicians and nurses. Because a withdrawal of accreditation by the Joint Commission leads to discontinuation of Medicare payments to the hospital, and therefore to its almost certain closure, hospital administrators understandably consider Joint Commission regulations to be extremely important, and not uncommonly initiate their own requirements in an attempt to demonstrate that they are trying to comply with the Joint Commission's demands to the best of their ability. Between the Joint Commission's requirements and the additional self-imposed institutional requirements, physicians and nurses end up carrying an enormously time-consuming burden simply to demonstrate their eagerness to comply with regulations that have no evidence of any beneficial effect on patient outcomes, and that have to be carried out at the expense of the time they would prefer to spend caring for their patients.³⁵

Graduate Medical Education

The Accreditation Council for Graduate Medical Education (ACGME) accredits graduate medical training programs throughout the country. There are currently more than 8,800 such programs in the U.S.³⁶ Trainees in these programs are highly accomplished individuals who have graduated from medical schools and may be eligible for a license to practice medicine independently. In the case of subspecialty programs, they have also completed a postgraduate program and may have become board-certified in one of the broad specialty areas (for example, a trainee in endocrinology is commonly board certified in internal medicine). And yet, ACGME requires that these highly accomplished persons be continuously evaluated not only for the knowledge of their chosen subspecialty and their patient care skills but also for four additional "competencies": professionalism, communications, problem-based learning, and system-based practice.

More than 111,000 trainees in the country are evaluated for the six competencies by the program faculty, sometimes as often as on a monthly basis. Additionally, the "180-degree" approach involves faculty evaluations by the trainees and "360-degree evaluations" are undertaken so that trainees can also be evaluated by their patients, peers, support staff, etc. An enormous amount of paperwork is generated.

To what end is all this activity? The trainees' knowledge of their specialties will typically be evaluated at the completion of their training by their specialty board examination. No other evaluation is truly necessary, and there is no evidence that the time-consuming and expensive "six competencies" approach results in training better physicians.

ACGME is also involved in regulating residents' work hours. The movement to limit the hours was spurred by the tragic case of a young woman who died at New York Hospital in 1984.³⁷ The patient's father, a prominent lawyer and journalist, claimed that his daughter's death resulted from a medical error that occurred because two residents on duty were at the end of a long shift, were taking care of too many patients, and were therefore too fatigued to think clearly. None of these allegations was ever proven, and

after years of court proceedings, in 1991 the state's appeals court cleared the records of the two physicians of the finding that they provided inadequate care in this case. Nevertheless, a commission established in response to this case recommended limiting residents' working hours, and these limitations became law in New York State. Later, ACGME accepted similar limits and made them mandatory for post-graduate medical programs throughout the country. These regulations have made it necessary to have patient care transferred from one team of residents to another more often, creating an environment for additional errors during the numerous transfers.³⁸ Majorities of residents and program directors find these changes useless.³⁹

There is no evidence that limiting residents' hours has had any positive effect on patient outcomes. In fact, an article contained in a 114-page booklet issued by ACGME in 2011, devoted entirely to the issue of limiting residents' hours reports that, of the clinical studies that have examined the impact of limiting residents' hours on patient outcomes, only one-third demonstrated benefit⁴⁰—hardly convincing evidence on which to base a nationwide regulation. It was also noted that, "On the whole, much of the discussion...is characterized by strongly held positions and limited evidence."

Electronic Medical Records

Another important example of bureaucratic decisions requiring major systemic changes without convincing evidence of benefit is government's policy to force introduction of electronic medical records (EMRs) into physicians' offices and hospitals. The federal government plans to spend at least \$80 billion on this effort. In addition, many institutions and physicians in private practice will spend their own funds (for example, the University of Pittsburgh alone is planning to spend \$1 billion on its EMR-related systems.) The reason given for these efforts is the supposed multitude of benefits from EMRs. These allegedly include great cost reductions by redundant service elimination, improved communication, reduction in medication errors, and other benefits.

However, the cost-effectiveness of the EMR is difficult to assess because of the high cost of acquiring, installing, and maintaining it, and at best it may end up being "a wash." 11,42

Although occasional reports opine that use of EMRs is associated with "higher quality," such association does not prove that EMR use is the cause of improved quality of care. Having reviewed studies on the subject, Doctors Groopman and Hartzband of Harvard Medical School concluded that, because of the lack of evidence, the government's predictions of EMR benefits amount largely to "wishful thinking." In fact, in September 2011, the UK's National Health Service dismantled its \$17 billion information technology project whose goal was, among other objectives, to computerize all patient records. One of the reasons given for the dismantling was that the project "has not and could not deliver to its original intent."

A study that addressed both cost reduction and quality improvement related to EMR use found no significant benefits when hospitals introduced full-featured electronic records.⁴⁶ It is

also well known that the introduction of EMRs leads to a substantial "slow-down," i.e., a reduction in the number of patients seen in the practice. As far as medication errors are concerned, a recent study concluded that the error rate in electronic prescriptions, about 12 percent, equals the error rate in handwritten prescriptions.⁴⁷

Perhaps because it has recognized EMRs' significant limitations, the federal government has developed criteria for EMR "meaningful use"—criteria that have not been examined for any evidence of usefulness. According to a recent survey of chief information officers of medical institutions, 90 percent of them have "serious concerns" about "meaningful-use" criteria, ⁴⁸ and a recent article in the *New England Journal of Medicine* stated that "it remains to be shown that the standards that are being established will result in improvement in care" or reduction in costs. ⁵⁰

Finally, both physicians and patients experience great distress from the EMR interference in their relationship.³⁵

In summary, it appears that the push for EMRs is driven by bureaucratic considerations and, perhaps, by the government's desire to obtain information on patterns of care and outcomes in clinical practices throughout the country. However, to quote one expert, "Do we need data on every American or intensive data on 500 people?" It is disingenuous for the government to force physicians and patients to provide data under the pretext that the EMR will benefit them.

What Is To Be Done?

What can be done to prevent further Sovietization of American medicine? First, I propose a moratorium on all new regulations by any governmental and/or quasi-governmental agencies involved in regulating medical practice, education, or research, unless extraordinary new circumstances (for example, a major epidemic by a previously unknown infectious agent) arise.

Second, all existing regulations by such agencies—health departments, CMS, the Joint Commission, ACGME, etc.— should be reviewed for evidence of benefit. Those regulations with evidence of benefit should be retained; those that are not evidence-based but are considered extremely important in terms of patient safety may be temporarily retained while evidence is gathered; and those for which no evidence of benefit is found should be eliminated.

Regulators should also review all existing regulatory organizations for duplication. For example, regulation of postgraduate medical education programs can be left to specialty societies and boards, since they already administer the final examination during which the candidate demonstrates competence to become board-certified in a particular specialty. ACGME is redundant.

Finally, instead of complying mindlessly with the avalanche of new regulations and non-evidence-based maintenance of certification burdens, physician organizations should insist that the agencies and organizations promulgating new rules be forced to provide independent objective evidence of benefit to patient care. Physicians, and the medical organizations that represent them, have an ethical duty and obligation to oppose unnecessary bureaucratization of medicine.

Interestingly, not unlike the title character in Nicolai Gogol's story "The Government Inspector," the inspectors usually live at the expense of the "inspectees." For example, 86 percent of ACGME's income is derived from the fees it charges the training programs to administer the inspections of these programs. Truly, to quote another Soviet proverb, "we create our own obstacles and then take pride in overcoming them." Progress in medicine will come from advances in science, not from bureaucratic interventions. We still have the ability to speak up and to oppose regulations when we consider them mistaken. This ability to speak up is what distinguishes us from the citizens of the extinct Soviet Union. If used appropriately and with courage, this ability will allow us to break the seemingly unstoppable attack of Soviet-like forces on the great fabric of American medicine.

We shall overcome.

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