As I have just passed my 90th birthday, writing this essay reminds me of Machiavelli’s admonition when he was receiving final Communion on his deathbed. “Renounce the devil and embrace the Lord,” intoned the priest. A long silence. Then came Machiavelli’s whisper: “This is no time to make new enemies.”

Let me start with a confession: I not only harbored dangerously unorthodox views during my career; I practiced them. Being allowed to voluntarily retire from the practice of medicine in 2007, rather than having had my medical license revoked decades earlier, was either an egregious establishment oversight or an act of divine intervention. Though my medical transgressions were never obfuscated or hidden, few are aware of them.

My deviant behavior consisted of sharp departures from the accepted norms of medical practice. I deemed such behavior an act of civil disobedience, for which I was ready to accept punishment. Yet sadly no one in or out of authority took note.

So what is this all about? If you are not in the health profession, I urge you nonetheless to wade through the swampy terrain of medical jargon. (The endnotes aim to clarify some obscurities of medicalese.) This essay addresses the onrushing industrialization of health care, a critical issue for the long-range well-being of the United States. Forty years ago I stopped referring most patients with stable coronary heart disease (CHD) for cardiac angiography.(1)

This procedure permits visualizing the extent of obstructed coronary arteries. What occasioned my deviation? The problem was that nearly all those undergoing angiography ended up having surgery, namely, coronary artery bypass grafting, or CABG (pronounced “cabbage”).

What could be wrong with improving blood flow to the heart by unblocking an obstructed or narrowed artery? Such a seemingly commonsense approach would have had the approval of every plumber who encounters a blocked faucet.

But, first of all, the heart is not a plumbing fixture. When a coronary vessel is narrowed or blocked, the heart has a built-in defense mechanism: It develops a collateral network of small vessels to compensate for the diminished delivery of nutrients and oxygen.

Overcoming an anatomic obstruction by surgical tinkering, or later with stents, may actually not be of benefit. Whatever the convictions of clinicians, all practice must be legitimized by evidence. Without evidence, medical practice lacks scientific sanction. Therein resides a second objection for the rush to CABG. No evidence existed that CABG improved both survival and the quality of life more than the optimal medical treatment for patients with stable coronary artery disease.(2)

Without such evidence the common resort to coronary artery surgery rested on a thin reed of presumption rather than on a solid foundation of unimpeachable data. This was not a “six of one, half a dozen of another” choice. The consequences of intervention were sobering. CABG was not an innocuous procedure. It carried an
upfront mortality as well as significant incidence of serious complications. In addition it added substantially to the cost of health care. Some years later coronary angioplasty and coronary artery stenting were introduced for the same purpose, again without supportive data.

So why did these procedures become so instantly popular? It must not be left unsaid that for some patients these interventions are miraculously life saving. But because they are extraordinarily beneficial for some with coronary artery disease, is it sound to infer that they benefit all comers?

**Coronary interventions**

Coronary surgical interventions were the first radical approach for overcoming obstructed coronary arteries resulting from atherosclerosis, the so-called hardening of the arteries. In 1967, the Argentine surgeon Dr. René Favaloro, working at the Cleveland Clinic, successfully used a vein graft to bypass an obstructed coronary vessel. Like Edmund Hillary and Tenzig Norgay, the first climbers to reach the summit of Mount Everest, or Roger Bannister, the first to run a four-minute mile, Favaloro opened a terrain deemed beyond human reach. In coronary artery vascular surgery he sundered the barrier to the seemingly impossible. Within ten years 100,000 patients were subjected to coronary bypass operations in the U.S.; by 1990s the number had quadrupled.

The rush to interventions multiplied still further with introduction of the far-less-invasive coronary artery angioplasty, wherein a thin balloon-tipped catheter is inflated at the site of a vascular narrowing. This percutaneous approach did not require anesthesia or opening the thoracic cavity. Soon came the further innovation of positioning a metallic stent, a veritable metallic scaffolding, to dilate and keep open a narrowed segment.

At present more than one million stents are implanted annually in the U.S. A majority of newly minted cardiologists have become adept interventionists. They spend full time in the catheterization laboratory, a place for experimenting with novel, challenging technologies and a veritable gold mine for hospital and doctors.

I am racing ahead of my story. In the 1970s coronary bypass grafting was the only available approach for directly dealing with an obstructed vessel. CABG, as already stated, was not innocuous. It carried a 2 to 5 percent operative mortality. The grafts tended to clot and obstruct. Ten years after the operation a majority had reoccluded. Reoperation was then associated with double-digit mortality.

Nearly 10 percent of patients undergoing CABG experienced some complications. Blood clots dislodged during the operation resulted in strokes and heart attacks. Undetected by cardiologists for many years was the impaired intellectual function afflicting many. It manifested in subtle memory losses and mild depression. I missed these complications until alerted by several spouses of patients. As one succinctly stated, “My husband is physically normal, but he isn’t the guy I married.” Surprisingly it took a decade or longer for these disabilities to be recognized. A published study on magnetic resonance imaging found that 51 percent of those who had CABG demonstrated some brain damage.
Fear facilitates medical interventions

One might wonder why patients acquiesced to undergoing a painful and life-threatening procedure without the certainty of improving their life expectancy. I have long puzzled at such acquiescence. Surprisingly, patients not only agreed to the recommended intervention but commonly urged expediting it. Such conduct is compelled by ignorance as well as fear. Patients are readily overwhelmed by the mumbo-jumbo of medical jargon. Hearing something to the effect of “Your left anterior descending coronary artery is 75 percent occluded and the ejection fraction is 50 percent” is paralyzing.(5) To the ordinary patient such findings threaten a heart attack or, worse, augur sudden cardiac death.

Cardiologists and cardiac surgeons frequently resort to frightening verbiage in summarizing angiographic findings. This no doubt compels unquestioning acceptance of the recommended procedure. Over the years I have heard several hundred expressions, such as: “You have a time bomb in your chest” and its variant “You are a walking time bomb.” Or, “This narrowed coronary is a widow maker.” And if patients wish to delay an intervention, a series of fear-mongering expressions hasten their resolve to proceed: “We must not lose any time by playing Hamlet.” Or, “You are living on borrowed time.” Or, “You are in luck — a slot is available on the operating schedule.” Maiming words can infantilize patients so they regard doctors as parental figures to guide them to some safe harbor.(6)

The power of such verbiage was brought home to me in the early 1970s by a Florida couple. The wife, Marjorie, did all the talking. It was quite evident that her husband, Bill, was too disabled to provide a coherent story.(7) The right half of his body was limp, his mouth sagged and drooling, his speech an incomprehensible jabber. Marjorie, a youthful-looking woman in her 60s, stumbled over words in a hurried animated outpouring of staccato sentences. She was impatient to bring me quickly into the loop as though I could offer a magical remedy for her disabled husband.

Bill had been in vibrant good health. Two years earlier, having reached age 70, he retired and devoted much time to long-neglected hobbies. Preeminent among these was playing 18 holes of golf twice weekly with former business friends. One Friday morning Marjorie was taken aback to learn that Bill was heading for a cardiovascular checkup to a world-renowned medical center that had recently established an outpost in Florida.

Bill denied any symptoms. The reasons he offered for scheduling this appointment were that he had never had a heart checkup and the flood of advertisements from the new center made him realize that prevention was far preferable to coping with a heart attack or worse. He discouraged Marjorie from “schlepping along,” certain that he would be back by lunchtime.

When Bill had not returned by noon, Marjorie’s anxiety mounted. She telephoned the medical center but was shuttled between prerecorded messages. At two o’clock she received a call to come immediately to the clinic.

She arrived at the cardiologist office more dead than alive. Her husband, normally outgoing, was silent and contemplative, and greeted her with a wan smile. The doctor explained that Bill “failed the exercise test,” but was fortunate that there had
been an opening in the catheterization laboratory, where he underwent an emergency angiogram. As the doctor had suspected, he had serious multivessel coronary artery disease.

For Marjorie the afternoon is buried in a deep haze. On a view box the cardiologist demonstrated the findings. These looked to Marjorie “like white strings knotting and suffocating the heart.” She inquired as to the urgency of the condition. The cardiologist responded that this type of anatomy was associated with an “impending heart attack or worse” and advised early CABG. Marjorie pleaded with the doctor to arrange the operation as soon as possible.

The doctor scheduled bypass surgery for the next morning. He again congratulated Bill for his good fortune, there being an opening in a tight surgical schedule. Everything went as planned except that interoperatively Bill sustained a massive stroke.

Deeply upset by her tale and knowing full well that there was no remedy to reverse the brain damage, I posed a question that was both insensitive and dumb. I asked, “Why didn’t you seek a second opinion?” She leaped from her chair shouting, “That is a stupid, stupid question, Doctor. When your house is on fire, you do not ask for a second opinion! You call the fire department.” She was absolutely right on all counts.

Medical records of Bill’s clinic visit in Florida showed that he was able to exercise for ten minutes adhering to a standard treadmill protocol. The coronary angiogram demonstrated only moderate multivessel narrowing. He had been completely asymptomatic and physically unlimited prior to the operation. These findings indicated that Bill could have been managed medically with the likelihood of a nearly normal life expectancy.
Why foster fear?

Why do cardiologists indulge in fear mongering? The reasons are multiple. One factor, I believe, relates to control. With the medicalization of society and patients’ growing awareness of overtreatment, doctors are no longer regarded as impartial counselors deserving complete trust. To protect themselves, patients engage in a number of maneuvers to gain medical know-how. They forage the endless medical pastures of the Internet, peruse extensive health information from a variety of sources, and shop for second opinions.

A physician soon learns that a “realistic” formulation shuts off questioning and saves time. “The cyst on the CT scan may be cancerous” or “one of the main coronary arteries is 50 percent obstructed” dissipates doubt about a doctor’s expertise. Cardiologists are aware that the medical technology in a catheter laboratory is awe inspiring. The resulting angiogram is like Mosaic holy writ emanating divine authority. The doctor so armed need no longer brook doubt or contradiction. Even obstreperous patients acquiesce and grow lamb-like.

Another reason doctors counsel patients to undergo interventions is that, invariably, they are true believers of what they communicate. Often, though, they think like plumbers rather than like scientists. A blocked pipe has to be unblocked. In the case of the heart, the sooner the better. Such medical opinions, though seemingly propelled by common sense, are not supported by clinical evidence.

When a coronary artery completely obstructs, it causes either loss of viable heart muscle or sudden death. It is reasonable to assume that a coronary artery 90 percent narrowed is at greater risk for occluding than an artery with a less restricted lumen. Such a view persuades doctors to recommend interventions to improve flow. However, human logic does not accurately reflect cosmology or biologic processes. It commonly turns out that the vessel responsible for a heart attack is but modestly, if at all, narrowed. Surprisingly, when a 90 percent obstructed vessel totally occludes, it may neither inflict further heart muscle damage nor provoke symptoms.

What has been learned is that the cause of an acute coronary event is the inflammation and rupture of the thin covering of an atherosclerotic plaque. When this covering ruptures, the plaque empties, provoking clotting and abruptly obstructing a previously widely patent vessel. The heart is unprepared for such an abrupt denial of nutrients and oxygen. By contrast, a slowly obstructing vessel promotes the formation of a network of small collateral vessels. These provide alternate routes for blood flow, thereby protecting heart muscle viability when a diseased artery finally occludes.

The above is not merely theory. Clinical angiographic studies have found that arteries with minimal disease may obstruct, leading to a heart attack. When two coronary angiograms were carried out before and after a heart attack, the culprit vessel was not severely diseased in the first visualization. This was observed in 85 percent of heart attack patients!(8a,b) One would surmise that the lumen of vessels widened or grafted are not the ones that later cause mischief. It stands to reason therefore that coronary interventions in those with stable CHD might protect only a minority against either a heart attack or sudden cardiac death.
The major factor that seduces clinical judgment toward interventions, I am persuaded, is economic. Cardiologists’ income has skyrocketed since advent of interventionist coronary procedures. During the 1980s a cardiologist income grew by more than 50 percent, while that of internists stagnated. The two leading interventionist cardiologists in New York City based at the Mount Sinai Hospital and Presbyterian Hospital currently earn around $3 million annually.

At the very same time that procedures were rampant and growing, medical treatment was profoundly changing. A host of risk factors for CHD could now be reversed by lifestyle changes and new pharmaceuticals.(9)

The “unethical” study

During the early 1970s I was impressed by new therapeutic possibilities presented by preventive strategies and agitated by the increasing resort to halfway technologies. The adverse human consequences of overtreatment troubled me far more than the economic costs. Many patients were forfeiting their well-being and even their lives. For a small subset of patients with coronary artery disease, a surgical intervention was necessary for assuaging symptoms and prolonging life. But for the majority available medical measures could provide a nearly normal life expectancy of unencumbered living.

Visualizing the coronary anatomy was a prerequisite for CABG. Angiography is regarded as a seemingly innocuous procedure. One soon learns in doctoring that medical interventions are never complication-free. Shaping my clinical judgment were several patients I had encountered who experienced devastating consequences from coronary angiography.

I was distressed by one patient in particular. G.B. had been a successful professor of dentistry with stellar accomplishments. One day while playing tennis he experienced oppressive chest discomfort. He dismissed this as due to a strained muscle, reasoning that at 48 years of age, without a family history of heart disease and without cardiac risk factors, the discomfort was best ignored. When he related what happened to his wife, she grew agitated and insisted that he consult a cardiologist. A brief workup indicated that the episode was most likely heart related. A cardiac catheterization with coronary angiography described to him as “absolutely without risk” was scheduled a few days later. During the catheterization he suffered a massive cerebrovascular stroke. He was left with markedly impaired speech and an abrasive personality. His professional life was ended.

I first saw G.B. as a patient twenty years later. He was now afflicted with severe angina pectoris, but had not seen a cardiologist since the traumatic episode. He raged against the medical profession. Living out of state, he came once or twice annually. I dreaded his visits. I was not spared his bursts of anger against doctors. Often G.B. expressed a wish to have died at the time of the stroke. Episodes of angina grew in frequency and were unresponsive to nitrates and a panoply of other drugs. I was certain he needed bypass surgery preceded by coronary angiography. I lacked the courage to raise this until gaining his trust as a human being and physician. It took five years before we were friends. Eventually G.B. was persuaded
to undergo CABG. The operation was successful, but his life continued to be
charged with frustration and rage.

Dealing with the growing tide of interventions, most of which I regarded as
unwarranted, was morally challenging. To remain silent was complicit. To speak out
was to invite confrontation with a powerful and unforgiving establishment. One
pressing question was, how could we identify the subset of coronary patients that did
well without surgical treatment? To determine how to proceed entangled me in a
welter of contradictory views and emotions. One thing was certain, something
needed to be done.

Sometime in early 1972 Lown Clinic patients undergoing coronary angiography at
the Peter Bent Brigham Hospital (PBBH) were set to be randomized either to
medical or surgical treatment. The study was aborted before it began. Every patient
opted for CABG operation. We could have anticipated such an outcome. Once the
angiographers and medical house staff reviewed with patients the cardiac
catheterization findings, coached in the lurid prose then and now in use, the
trajectory of further care was unalterably fixed. Not a single patient agreed to
participate in the randomized study. My words hit a brick wall.

It became evident that angiography was a funnel, a way station to a predetermined
goal. Its prime purpose was to guide surgeons to narrowed or obstructed coronary
arteries. To diminish the use of CABG for patients with stable CHD required
bypassing coronary angiography.

We therefore determined to study stable CHD patients having advanced disease
without subjecting them to angiographic investigation. Without viewing the coronary
anatomy, how could we be certain that the selected patients had advanced disease?
An extensive cardiovascular literature affirmed that the capacity to exercise on a
motorized treadmill and the ensuing electrocardiographic changes indicated the
severity of coronary vessel obstructions.

Patients selected for the study adhered to a distinctive medical program. Risk factors
were punctiliously attended to. Hypertension control was high on the therapeutic
agenda. We prescribed the free use of sublingual nitroglycerine for managing angina
pectoris.(10) We discouraged early retirement from productive and satisfying work.
We openly discussed with both patient and spouse the threat of sudden cardiac
death that haunts a majority of those afflicted with coronary heart disease. We were
unequivocally reassuring on this score.(11)

We addressed social and family problems and opened dialogues about significant
psychosocial stresses. We minimized shuttling patients to specialists and kept
procedures and interventions to a minimum. Foremost, doctors spent much time
listening, thereby fostering trust and an adherence to prescribed lifestyle changes.
We aimed to be holistic practitioners, not merely heart doctors. In short, we did as
much as possible for the patient and as little as possible to the patient. Above all we
avoided medicalizing our patients, so instead of living for their disease, they
continued to live fully despite their disease.

We aimed to identify early warning symptoms and signs of changes in disease
status, allowing ample time for appropriate interventions. The paramount question
was whether medical management affected adverse outcomes of coronary heart disease such as sudden cardiac death, heart attacks, or the development of congestive heart failure. At the same time we were not Luddites. When the coronary condition changed, appropriate interventions, including CABG, were undertaken.

As the study got under way and participating patients multiplied, I became increasingly concerned about malpractice suits. In the climate of our time it was easy to conjure all types of adverse scenarios resulting in a class action suit launched by a bevy of aggressive attorneys. Not abiding by the prevailing standard of care was tantamount to negligence, a major factor in litigation. It would take but a single case of sudden death or a heart attack in a patient denied coronary angiography and CABG to launch a nightmare. If several of our patients were so afflicted, one could conceive a public scandal with dire results, including the forfeiture of hospital privileges and a license to practice medicine. There would be no shortage of plaintiff witnesses from esteemed institutions around Boston.

In the early hour of morning, when sleep denudes reason of reasonableness, I was haunted by the likelihood of incarceration for manslaughter. These perturbing ruminations were not helped when a cardiology colleague accused me of indulging in unethical medical practice. He asked, “How would anyone regard a doctor who denied a chest X-ray to a patient coughing up blood because of some cockamamie theories?” I imagined he was accusing me of criminal negligence behind my back.

**Results only a Pangloss would believe**

We had no difficulty in recruiting patients for the study. Many who had been urged to undergo bypass surgery were seeking a second opinion. In the first of four studies we carried out over the ensuing thirty years, we recruited 144 consecutive patients with advanced coronary artery disease.(12) These were followed for an average period of nearly five years, during which time 11 patients died, for an annual rate of 1.4 percent. We referred only 9 patients for CABG (1.3 percent annually). These results were better than the best outcomes being reported for those undergoing CABG. We concluded that resorting to cardiac surgery was infrequently indicated for patients with stable CHD.

Our sense of achievement was short-lived. Leading medical journals refused to publish these findings. The study was faulted for lacking angiographic data. It was averred that without such information about the coronary artery anatomy our results were uninterpretable. A number of medical journal reviewers suggested that the reported favorable outcome indubitably reflected the selection of patients with mild or no heart disease. This notwithstanding that a majority of the study population had suffered heart attacks, experienced angina pectoris, and developed profound electrocardiographic changes during exercise stress testing.

It took four years before the *New England Journal of Medicine* published our findings. A flurry of angry letters followed with the recurrent motif that without coronary angiography our conclusions were invalid. For the first time in my medical career I received phone calls from outraged physicians accusing me of abandoning science or of setting cardiology back to the Dark Ages.
To address the major criticism of our first study, we launched a new investigation limited to patients with angiographically confirmed severe multivessel coronary artery disease. Though an Herculean task, it was made possible by the fact that medical insurance companies were beginning to demand second opinions before reimbursing for CABG. This was intended to contain the surge in costly cardiac operations. We recruited a small population of 88 patients, of whom 63 had significant narrowing of all their major coronary arteries. During twenty-eight months of follow-up we encountered no deaths and referred only 14 patients for CABG (7 percent annually). These results, though published in a leading medical journal(13), gained no attention in the mainstream media and evoked no interest among cardiologists or in the health policy community.

Introduction of percutaneous transluminal coronary angioplasty in the 1980s wrought a revolution in treating obstructed coronary arteries. This procedure involved threading a balloon-tipped catheter through a peripheral artery to the narrowed coronary segment. Inflating the balloon widened the lumen, thereby reducing the blockage.

Angioplasty was a wondrous technical achievement with substantial clinical advantages over CABG. It avoided surgery with its many potentially adverse byproducts resulting from anesthesia and thoracotomy as well as perioperative complications, a longer hospitalization, and a slower recovery. The salutary cardiac outcomes were similar. As with any medical intervention, angioplasty was associated with rare fatalities and some complications, a few of which were disabling. Troublesome was that the dilated vessel frequently reobstructed with adverse consequences.

The competition between angioplasty and CABG roused a turf war between cardiovascular surgeons and interventionist cardiologists. The competition contributed to lowering the threshold for interventions. New syndromes were devised justifying a rapid transit to either a catheterization laboratory or an operating suite. The shibboleth diagnoses became either “unstable” or “intractable” angina pectoris. In the new climate of market medicine, a complaint of chest discomfort or the use of an extra nitroglycerine was sufficient for a diagnosis of “unstable angina” and for being routed to the catheter laboratory.

Interventionist cardiologists were so charged with conviction of their benefactions that many largely asymptomatic men, merely on suspicion, had their coronary anatomy surveyed. Of course the outcome was preordained. Most middle-aged Americans have coronary artery narrowing. The rush to procedures was spectacular. By mid-1980s 30,000 patients had undergone percutaneous angioplasty. Within five years the procedure grew tenfold. With the introduction of coronary artery stenting, procedures reached a million annually.

In an era of mega-interventionist cardiology, it was essential to reexamine the comparative robustness of a medical-management approach. For the third study(14), the Lown Clinic recruited 171 second-opinion patients, previously counseled to undergo an intervention. During four years of follow-up, outcomes were identical to our earlier reported results. Once again our findings were dismissed as meaningless due to a small sample size.
We were determined not to be silenced.

From 1992 to 2000 we screened 2,598 patients, of whom 693 were eligible and consented to participate. Their mean age was 67, the oldest reported group.(15) Half of these patients had been urged to undergo a revascularization procedure. During an average follow-up of 4.6 years, the cardiac event rate was extraordinarily low, with an annualized mortality of merely 1.4 percent, identical to the outcome we had reported twenty years earlier. Referral for interventions, namely CABG and coronary stenting, was 6 percent annually, a tiny fraction of the massive traffic for costly and unwarranted procedures.

Four decades of persistence, some would call it pigheadedness, availed us not a whit in gaining visibility for an approach that we believed improved health care and substantially contained medical costs. Notwithstanding the prevailing widespread concern with runaway health care costs, neither the media nor the health care establishment evinced any interest. No one came Knocking at the door to examine our practice or our outcomes.

The challenges we were posing were not merely clinical and economical. Ultimately the issues we raise are profoundly ethical. A new treatment, whether involving drugs or procedures, is improper without indubitable supporting evidence of benefit. The patients’ well-being must not be compromised by imagined good when countervailing interests are at the same time being served. Our forty-year struggle essentially concerned medicine’s first and inviolate principle, primum non nocere. “First do no harm” is the litmus test sanctioning the privilege to practice medicine.
Notes

1. The large majority of patients have stable CHD. Generally a middle-aged man experiences chest tightness while engaging in excessive exertion or exhibits electrocardiographic changes when undergoing diagnostic exercise testing. When coronary risk factors are addressed through lifestyle alterations and with appropriate medications, the patient may anticipate a long survival.

2. The first randomized study was published in the leading cardiovascular journal in 1983, sixteen years after Favaloro’s description of CABG (Coronary Artery Surgery Study (CASS), Circulation 1983; 69:939-950). This study found no difference in outcome between medically and surgically treated patients except in a small subset of around 10 percent. This important publication did not rein in interventions, and CABG procedures continued to escalate.


5. In someone without symptoms, such findings do not warrant any intervention. They do mandate a well-structured medical program focused on lifestyle changes to reduce CHD risk factors.

6. This subject is dealt more extensively in The Lost Art of Healing, Chapter 5, “Words That Maim.”

7. This case is reported in the Lown Forum, titled “Harm of Unwarranted Tests, Procedure and Treatments,” October 2010.


9. Reducing salt intake and taking antihypertensive drugs reduce blood pressure; lowering dietary fat consumption, along with a host of new drugs, reduced blood cholesterol; diabetes was also better managed. A revolution in therapy was afforded with the introduction of beta-adrenergic-blocking drugs that damped sympathetic nerve traffic to the heart.

10. Encouraging the free use of nitroglycerine puts the patient in control, thereby diminishing uncertainty as well as anxiety. My great teacher, S.A. Levine, commented that the patient who uses nitroglycerine freely and abundantly outlives his doctor.

11. We found that patients who showed no advanced forms of arrhythmia during 24-hour heart monitoring and who were able to exercise more than eight minutes adhering to a standard protocol without evoking heart rhythm abnormalities, experienced no sudden cardiac death during the ensuing year! This provided a basis for optimism to be communicated to patient and spouse.


