

# A Tale of Two Crises

Robert L. Nuckolls, III  
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November 30, 1999 issue of *USA Today* carried the following articles. . . lined up side by side right on the front page. I'll invite you to read as follows:

## Medical mistakes 8th top killer . . . .

By Bob Davis  
and Julie Appleby  
USA TODAY

Medical errors kill more Americans than traffic accidents, breast cancer or AIDS, Institute of Medicine officials said Monday as they called for a sweeping "systems" approach to make medicine safer.

"These horrific cases that make the headlines are just the tip of the iceberg," says the institute's report, *To Err is Human*. Estimates range from 44,000 to 98,000 deaths a year attributed to medical mistakes, making it the eighth leading cause of death.

The errors include giving the wrong drug to incorrect diagnoses. The report estimates that such errors cost the nation \$8.8 billion a year.

The institute, an independent body that makes recommendations on medical matters, called on Congress to finance an attack on the causes of errors and seek a 50% reduction in errors within five years.

"We can do this," said Brent James, one of the report's authors. "The majority of these are not true human error but classic systems failures."

The plan follows the approach in aviation, in which errors can be reported without fear of punishment.

"No person goes out and intentionally damages a patient," said Nancy Dickey, former president of the American Medical Association. "But when an error occurs, it's important you learn from it."

To build "a culture of safety" the institute calls for:

\* Congress to create a national Center for Patient Safety that would track errors and promote research.

\* Two nationwide error reporting systems: one mandatory, the other voluntary.

\* Increased attention to safety at the Food and Drug Administration.

William Richardson of the Institute of Medicine committee said errors are unacceptable in a medical system that promises "first to do no harm."

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## FAA to begin special audit of Boeing

By David Field  
USA TODAY

The Federal Aviation Administration will descend on Boeing's major factories Thursday for a nearly three-month special inspection of the company's quality-control systems.

The FAA will review the manufacturing process at the factories in Seattle, Everett and Renton, Wash., where almost all Boeing jets are built.

The audit will cover everything from parts to how Boeing makes engineering changes.

The FAA's action comes after Boeing reported "slips in different areas of the production system," said Beth Erickson, the FAA's head of aircraft certification.

After the audit ends Feb. 29, Boeing could be fined, she said. The audit probably won't ground jets but could delay deliveries of new ones.

"If so, so be it. Safety is paramount," Boeing spokeswoman Susan Bradley said.

The audit comes after the crash Oct. 31 of a 767 flown by Egypt Air. All 217 people aboard were killed when Flight 990 plunged into the Atlantic. Investigators have not determined that any mechanical flaws caused the crash.

However, one of the problems prompting the FAA audit stemmed from an American Airlines report that two of the 16 bolts holding a vertical stabilizer on a 767's tail were loose. Improperly calibrated tools caused that problem.

Boeing also recently halted delivery of about 50 jets to replace a condensation shield that had been improperly applied to cockpits.

None of the problems led to an accident or incident. Boeing has corrected the problems already identified. Erickson said.

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First, take note of the fact that these articles are about two of the most heavily regulated industries in the United States. Consider also that the actions in response to these conditions involve agencies of government, old ones and new ones yet to be created. Given that these articles were found on the front page of a prominent newspaper, I wonder how many people reading this think these conditions are "news" . . . consider how many times in past years have we read nearly identical stories.

Understand further that the latest quality mania to sweep the universe is to seek certification under the "ISO 9000" an internationally adopted set of rules designed to earn the consuming public's confidence by stating: (1) "We've written down rules that cover every aspect of our business" and (2) "We promise to observe each those rules with religious fervor."

Check out the web site and marketing literature of every aviation manufacturer or supplier of medical goods and services and you'll very likely find the "ISO 9000 Certified" medallions prominently and proudly displayed. These claims to purity of thought and action are in addition to hundreds of pounds of regulatory documents in place long before the concept ISO 9000 gleamed in the eye of the world's career bureaucrats.

Gee, if these institutions are already regulated, inspected, licensed, approved, certified, and sprinkled with holy water, what's going on?

### A call to arms?

Look these articles over more closely and we find phrases like: . . . *a sweeping "systems" approach to make medicine safer. . . . not true human error but classic systems failures . . . . a culture of safety . . . . The audit will cover everything from parts to how Boeing makes engineering changes.* I observe that none of these statements or any part of either article speaks to the actions of people. Both writers paint pictures of systems failures.

Response to this "crisis" was predictable: A December 7 *USA Today* story by Susan Page describes the administration's call to arms. The President is going establish a "new federal agency to collect data on medical mistakes and develop recommendations to avoid them." This committee has but 60 days to report directly to Vice President Gore with "new strategies to protect patient safety. We all breathe easier now . . . the presidents are on the job. They're going to fix everything. Wow, a solution in only 60 days? Hmmm . . . I'll bet it will be mere weeks before Mr. Gore's campaign speeches begin to give him credit for having saved thousands of lives . . . because he headed up a committee on this "critical new initiative."

How many new bureaucrats will be hired for this task? Would ANYONE not be in favor of patient safety? Would any congressman in his right political mind not vote for PLENTY of your and my dollars to fund this new effort? The distressingly relevant question is, "How can any cadre of new policemen guarantee the actions of millions of health care workers?"

Every bureaucrat will tell us, "Problems like these cannot be understood until all incidents are recorded, tabulated and analyzed so that appropriate changes can be made." It's not surprising therefore that government suggests creation of TWO reporting systems (It cites some experience with an aviation reporting system).

An extensive Wall Street Journal article for December 6, 1999 cited instances where air traffic controllers are suspected of sweeping reports under the rug and even tinkering with how data is displayed and recorded to hide violations of the rules. Errant controllers ultimately discovered were fired or demoted. The culture within the controller's workplace, all but guarantees serious consequences to his career and working conditions. So . . . exactly how will this new reporting medical reporting system work?

Consider the phrase, "*increased attention to safety by the FDA.*" Unless there are thousands of FDA employees already standing around with nothing to do, where will they get the numbers of folk needed to implement this "increased attention" . . . you got it, we'll hire 'em. Need more dollars? No problem! Gotta rise to the occasion here. Costs are not valid constraints when it comes to patient safety.

The Boeing story tells us that for 90 days, a cadre of people whose salaries are paid from your paychecks will fan out through the plant, alert to the slightest hint of transgression. Transgression against what? Why the regulations, the rules, the policies and procedures. But what about the those ISO certified policies and procedures that made us flush warm and fuzzy about placing our lives and fortunes into the hands of those who produced the documents? I'm reminded of an oft quoted line from our society's past, "I know she's pretty but can she cook?" The modern political corollary might be, "I know they can write but can they build airplanes and administer drugs?" People on the front lines don't do the writing, and most don't have time to do much reading. Even if they were given the time, can we be sure they understand and will comply with what they read?

### Looking to Government for "Help" . . .

Consider all the whistle blower stories of national prominence. Have you ever heard of a whistle blower being rewarded for good citizenship while the transgressor receives proper chastisement, punishment or removal from power? If a patient croaks from a push of the wrong elixir into an IV, how many people are going to happily rush forward to share their knowledge of the accident in hopes this will never happen again?

Okay, let's allow the whistle blower to remain anonymous. Just fill out the form on FAA or FDA web sites. How many good folk will fall victim to pranks and vendettas as the result of forms fraudulently submitted? "*Culture of safety*"? More like a culture of informers . . . some will watch for a juicy tidbit to upload to the website after work. Others will withdraw into cocoons of privacy and safety, forsaking professional skills for non-threatening inaction. Better to become an administrator with no direct patient contact than to risk one's future by actually helping somebody. Increased government intervention will produce the same results observed in decades past - as people with real skills and integrity are driven away from society's most critical tasks.

Looking at aviation's latest crisis-in-the-making consider the author's words, "*The audit comes after the crash Oct. 31 of a 767 flown by Egypt Air.*" After every disaster, members and agencies of government scramble all over each other in a rush to ACTION! . . . Mere days after TWA800 went down, people in Washington decided that all postal packages over 16 ounces in weight bearing stamps had to be personally handed to a postal clerk. Individuals who possess postage meters continue to conduct their business by front porch or corner mailbox. But ordinary folk who licked their stamps had to travel to the post office and stand in line to mail packages.

The stupidity of this ruling comes to light when you consider (1) to this day, the real cause of TWA 800's demise is unknown. (2) What is the likelihood that an agent of the FBI will dangle charred and shredded remains of a package in front of a gathering of postal clerks - and produce instant identification of the individual who mailed it? (3) If a terrorist is smart enough to bring down an airplane, is he not also smart enough to acquire use of somebody's postage meter?

This simple ruling by people who mean well costs citizens of this country billions of dollars per year in compliance expenses. All for an effort that has no demonstrable benefit. None-the-less, fellow employees of Al Gore will lay claim to "saving hundreds of lives" for having created this gem of regulatory ineptitude.

Perhaps the Boeing story offers a more solid approach. We'll fine them. Yeah, that's it. Generate a list of all the slip ups we can document, multiply by \$5,000 each and wow! I'll bet a crew of hundreds working for 90 days throughout Boeing's facilities can work up quite a tab against Boeing.

Wouldn't be surprised if this effort doesn't fatten government's purse by tens of millions of dollars. The swarm of inspectors will walk out of the plant patting each other on

the back for "a job well done." Boeing will pull out the checkbook and pay the fine . . . and then what? Now all will be right with the world and we'll never again read about Boeing's inability to build safe airplanes? Well, maybe not until next year.

Has anyone considered that the wrong drug was given because somebody didn't read a document or label? Were the bolts loose because somebody didn't follow a documented procedure? Surely every potential hazard to the lives and fortunes of people are analyzed, procedures crafted and documents published to prevent that hazard from materializing. With the millions of documents already in place that guide us through life's maze of hazards, why do these things happen?

Up to now, you probably thought this essay was about hospitals that kill patients and factories that produce airplanes with loose bolts. May I suggest that these two stories are but the tip of an iceberg? You can scan the "news" any day and find repeating examples of government ineptitude. Consider the war on drugs where the more taxpayer dollars we throw at the problem, the more money flows into the coffers of drug lords. How about propping up a foundering education system? I've heard estimates of over 700 bills appropriating billions of dollars yet education continues to slide. And "managed" health care? Government created a monster and is now motivated to rescue us from it by creating still more rules and hiring people to write and enforce them. The list is endless.

I cannot offer the skills of a credentialed human factors psychologist but I'll bet you and I can pool some collective observations and deduce a few root causes of the problems these articles talked about.

### Ignorance Loves Company

Consider the state of our standards for education. Are you surprised that many of the people in our workforce cannot read well? Consider that life's experiences for children growing up in an outcomes-based education are enriched more with great balls of flame and destruction on the screen of a Star Wars movie than from books out of the library. The last time I sat foot in a middle school library, I pulled several dozen books off the shelves at random and checked the return date tab inside the cover. I could find no single book that had been checked out in prior 3-5 years! Are you surprised that few of our citizens have a convincing notion of what constitutes honor, or integrity, or pride in the professionalism with which they ply their craft?

How many of our national heroes are spotlighted for their intelligence, honesty, courage, honor or skills to make

meaningful contributions to peoples lives? Can one even become a national hero today for having conducted his or herself in an exemplary manner? Ask the whistle-blowers last featured in stories on *20/20* and *60 Minutes*.

On Sunday, December 20, 1999, 60 minutes featured two prominent physicians and showed us their willingness to stand up to mis-information and negligence by drug companies. Both doctors were highly regarded by their peers yet transgressions of the drug industry continued relatively unabated while the whistle-blowers were systematically threatened and vilified. Tell us again Mr. President, just how are these new reporting systems supposed to work?

None of this is news. It's been going on for decades and we're now seeing the results. Both the regulators and the regulated are becoming increasingly ignorant of physics, unable to do critical thinking and willing to accept the authority of others who are equally ignorant and fatally blind in their trust of still higher authorities. The regulators who throw up massive roadblocks to progress turn a blind eye to the misdeeds of those whom they propose to regulate.

We've lost command over choices in risk assessment and the ability to judge value returned on poorly conceived investments of taxpayer's dollars. Individuals in government are ecstatic when media keeps reporting each event as if it were a new problem. People rush around and set up news conferences to get their face on television and assure the public that, "everything's going to be okay. I'm right on top of this," and thereby justify expanding their power with the expenditure of more tax dollars.

We've witnessed a time when the highest authority in the land is more preoccupied with pleasure and personal power than with improving the futures our nation's citizens. We hold up our non-accomplishments with increasing pride while the greater whole continues a downward slide into chaos and regulatory paralysis.

Many people who administer drugs, tighten bolts and invent Internets are people who graduated from our school systems at perhaps as few as ten years ago. Those most successful at what they do are relatively independent of bureaucratic institutions; not bogged down in debilitating policies and procedures.

Independence? What a concept. How do we foster or even condone independence in things so important as aviation or medicine? I suggest we already have excellent examples of such independence in both systems. For example, suppose you're being treated by a rural physician whose nurse may well be his wife. What do you think the chances are that

you'll receive the wrong drug due to their lack of understanding or due diligence?

Consider too that more airplanes are being built in people's basements and garages than in all the factories combined. Airplanes built by-in-large by a single individual who knows little about the physics but is willing to learn. Individuals who take on a responsibility to install all the parts with proper bolt tightness. People who read the instructions not only once, but perhaps a dozen times and then seek advice of learned counsel if they're unsure. These airplanes are the best ever flown and government has nothing to do with their creation and maintenance.

Tiny examples to be sure but I think valid. In our rush to bring order out of chaos, we've created institutions staffed with people for whom there is no accountability. Rules, regulations, policies and procedures are churned out in great numbers but with no warranty either written or implied. Congress finds it easy to allocate money for programs with lofty goals but never seems to budget money to assess effectiveness of the program or shut off the flow of cash if the program is shown to be a waste of tax dollars.

If a regulatory action or policy does not produce the desired result, does anyone get their money back? No, it's more likely that even bigger and more creative solutions will increase the outflow of cash into the same, valueless pit. What's worse is that the cash is controlled by the same people who crafted the last batch of policies that produced no demonstrable benefits.

The first step toward salvation is for people to take back their independence. We've traded freedoms for convenience and security. The people to whom we entrust our security are more ignorant of science and critical thinking than many ordinary citizens.

The first job of government is to protect the people from government. People who swear to protect and uphold the Constitution should convince us they've read it. They should be willing to demonstrate that every action conducted on our behalf is measured against an understanding of words in the document they swore to uphold and protect.

Such a document is its own "protection" . . . it is not presently necessary for our lawgivers to stand with armed guards to protect the Constitution. They need only heed the words it contains and the document protects itself. Ignore the words and a time may come when people have to protect the document with gun in hand. Ignore the words and the document will become a threat to those in power who will seek to destroy it and re-write history to teach that

it never existed. How many times has this happened around the world? Never happen here? Ready to be your life on it?

Executive Orders crafted in recent years provide us with insight into President Clinton's frustration with the Constitution. Clinton's good friend Paul Begala said. "Stroke of the pen. Law of the land. Kinda cool." Executive Orders like 13083 allowed to go forward un-challenged will encourage a flood of similar breeches of constitutional law. It would not be long before agencies of government find it in their best interest to have the Constitution destroyed and wiped from public memory.

It wouldn't be difficult - and it gets easier with each passing year. Very few citizens today can relate to what the document means in their lives and fortunes. If the Constitution were re-written in style of Federalism offered by Executive Order 13083, it is estimated that fewer than 25% of our citizens today would understand the significance of the changes.

The second job of government is to acknowledge that simply putting words into a document does not make it so. The failure of ISO certification to guide us out of darkness demonstrates that ignorance of the human condition is not limited to governments! Laws must be constitutionally chartered. The tasks they define must be logical modifications to causes that demonstrably achieve the desired effect

Spending \$billions\$ on trips to the post office saves no lives - in fact it can probably be shown to increase deaths due to auto accident. Citizens are too ignorant to realize this while lawgivers will claim great value in yet another burden placed on their constituents - all in the name of public safety. Wouldn't it be a kick in the head if more people die in the name of making airplanes safe than the numbers that die in airplanes?

Further, laws must be written for people with the skills and intelligence to make them happen. Crafting a law and confiscating funds to implement it should not be carried out unless the precursor conditions are met.

If we continue sending people to Washington based on their good looks, TV personalities or stated goals to send more tax dollars back home, this decades-old downward spiral will continue . . . The more we depend on government to assuage our discomforts and misfortunes, the more ineptitude we'll empower. As ineptitude gains more control over our lives, unrest and dissatisfaction will increase. Inept systems feed themselves first and grow. Ignorance begets and protects more ignorance. Ultimately the system must marshal large forces to protect itself from angry citizens.

As I write these words there is a situation where the FAA has been made aware of science that explains why their radar systems too often don't work, in some cases as much as 90% of the time! Perhaps they dislike the personality of the whistle-blower. Maybe someone harbors a fear of becoming the token scapegoat. We'll probably never know. What we do know is that the bureaucrats are doing everything possible to stonewall and/or sweep the issue under the rug. Personalities and protection of careers are more persuasive than a value of the public trust. In the meantime, the taxpaying public believes the rhetoric found in every speech by an FAA official claiming to have public safety uppermost in their minds.

Unchecked, the outcome of our present course is to hire one ignorant policeman to stand over each equally ignorant citizen to make sure that all rules, regulations, policies and procedures in effect are dutifully observed. By the way, do you think that policeman is going to know how much the bolt should be tightened . . . how to fix a fussy radar . . . or how long the patient will live after the syringe hits bottom? Until those individuals who make their livelihood from the public's pockets summon honor and courage to live up to the oaths they took, the foundations and ultimately the structure which made this country great will continue to erode and finally fall.

## Real Solutions

There are forces which promote and forces that restrict honorable and successful citizenship. Many are easily deduced as I can demonstrate from personal observation:

About 20 years ago, a major manufacturer of aircraft in the US purchased an overseas design for an airplane for the purpose of building it in the US and integrating it into their already substantial product line of airplanes. A component critical to operation of the aircraft was designed and manufactured by a subsidiary of the original builder. Ownership of design for this critical component was retained by the overseas subsidiary after responsibility for the rest of the airplane had been assumed by the US manufacturer. The airplane's new builders sought the manufacturing services of a well known company to supply the part under a license from the original offshore designer.

I suggest that it's no stretch of concepts to consider that a license exerts the same kind of pressures as regulation or law. No matter how an agreement is called, parties to the agreement are bound to observe it under threat of government or civil retribution.

After decades of sales by the new manufacturer of the aircraft, it's painfully obvious that the critical component's

quality is poor. Failure rates are high. Warranty replacement costs accumulated over the years mount into the millions of dollars and customer dissatisfaction begins to have an obvious and adverse effect on the company's fortunes. All requests by the airplane manufacturer for assistance in fixing the problems were hindered first and foremost by one thing: a license issued by a third party having little if any interest in the fortunes of people who purchased the airplanes.

For nearly a decade, numerous tweaks and minor changes to the design were offered and implemented. Every change implemented on the airplanes were accompanied by an arduous task of complying with both business and governmental restrictions. The interval from conception to demonstration of each change was at least one year.

It was generally agreed by all parties that the design was marginal. The design was decades old. The technology used had long since been replaced with more modern methods on other airplanes. However, roadblocks to progress in the form of business and regulatory restrictions made the idea of total redesign and replacement too horrible to contemplate.

The company with the greatest ability to offer solutions begged off any responsibility, "we are building to the drawings of the design holder from which we cannot deviate without their permission. As long as we meet their requirements to the letter, we're not responsible for your customer's perception of your airplane." Using the license agreement as a shield from responsibility for customer satisfaction, the supplier of this product continues to sell new units and overhaul failed units. The situation stumbles on for years mounting millions of dollars in costs and incalculable damage from customer dissatisfaction.

Finally, the aircraft manufacturer decides to upgrade the component to a modern version and issued a request for quotation to potential suppliers. Reaction from the present supplier was predictable. Suddenly, they are willing to take over the design and make the necessary changes to improve the product's quality. After years of indifference and faced with the prospect of losing their cash cow, the supplier suddenly finds a new sense of urgency . . . fix this problem or loose the business.

This story illustrates how any restriction can affect free analysis and action need to solve problems. Documents created either by government or citizens need to be carefully crafted so that they produce desired positive effects. Laws, regulations, licenses, policies, rules and procedures may be crafted with the best of intentions, they often do have deleterious effects as well.

A regulation can set goals for performance but it can also create a ceiling. For example, codes for building a house are intended to establish minimum requirements but most contractors also view them as limits. "Hey, I've met all the codes. Nobody else is building houses any better. Why should I put in an extra effort? It will only make my product more expensive and hurt sales."

The same thing happens in hospitals, manufacture of airplanes, or the construction of houses. Workers in every profession are inundated with dozens if not hundreds of requirements ranging from policies and procedures to federal regulation. Disregarding any of these mandates puts the worker at risk . . . NOT for failing to do a good job but for failure to observe a rule. It's more important to comply with regulation than to compete in the marketplace by offering a superior product.

If you want to improve the performance of any institution irrespective of the size or numbers of individuals, it's quite simple. Watch the quality of their product and make their performance a matter of public record. Regulation and rules will never have so profound an effect as the realization that, "Gee, maybe we'd better fix this problem or we're going to loose the job!" It's funny how you get people's attention when continued paychecks are dependent upon successful performance of a task.

Regulation, policies and procedures will never replace education, understanding, pride in achievement and marketplace acceptance of a product's quality. Government can do only three things. Confiscate money, spend money and write rules with the threat of punishment for failures to comply. Aside from the construction of an interstate highway system, government has yet to offer the solution to any of society's most perplexing problems. Government's attempts to social engineer by legislation is a demonstrated dismal failure.

In the mean time, citizens are lulled into a false sense of security when politicians stand in front of TV cameras and assure us that, "help is on the way." Government's utterances about education in this country is pure lip service . . . if we become truly educated, the face of government in this country will change in ways that few people paid with confiscated dollars would appreciate.

It's safe to say that no salvation from ignorance fostered by government run schools is coming any time soon. In the mean time, those most affected by ineffectual and debilitating regulation, rules, policies and procedures will have to assume the battle's front line.

Find those among you who have taken it upon themselves to become educated. People who have read and understand the history of their craft. Like government, many who offer goods and services commit the same errors and re-invent the same wheels out because they are ignorant of what has gone before them.

Join them in critical review of impediments to progress. Sort the aspects of business, personalities and fate from the physics of the matter. A tool lacking demonstrable effectivity should be suspect until it's usefulness is completely known and understood. Lobby those who would regulate you with every intention of enhancing the public good. If they are ignorant of the physics by which safety and quality are enhanced, their efforts will only tax your time and resources in negative and sometimes disastrous ways.

Give individuals the freedom to exercise responsibility without fear of failure. The unwillingness of people to make a frontal assault on poor quality aircraft part I cited had to be exacerbated by fear of failure. Many times the dollars and time to fix the problem were squandered at the expense of the stockholders and customers. To this day, the problem has yet to be fixed.

Put an absolute end to punishment of "whistle blowers" for coming forward about any aspect of the business that needs attention. Learn to sort out the ranting of ignorant and/or disgruntled individuals from fact. Every bit of information needs to pass muster of critical review irrespective of its source. People who would become sources of information cannot be expected to make good suggestions if they are not involved in the critical review process and acquire some critical review abilities of their own.

Encourage your employees to become aware of what is done on their behalf in Washington. Unless we take the time to observe, pass judgment and react to bad law, nothing is going to change. Government will continue to grow and it's effects on the education and quality of life of our citizens will continue to erode.

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