

*Understanding the regulatory process placed upon medical devices is all but impossible, overwhelming to say the least. The majority of our readers have never considered the long road of a new device. From the investigator to the manufacturer, to the investigator, to the user, each step is painstakingly taken. We hope this autobiography will lend insight to the present dilemma.*

**The Editor**

## **The Autobiography of Joe**

**A medical device**

**Born: 1975**

**Died: 1983**

### *Prologue*

*My life is, as is so often the case, one that predates my memory; so I may get some of the circumstances of fortuitous conception, troubled gestation, stormy birth, and checkered career mixed up and out of sequence. However, my story is like those of many other devices that have been heralded as everything from bastards to "bundles from heaven." My autobiography speaks for many of my offspring and siblings.*

My name is Joe. I am a medical device. As with my brothers and sisters, during my conception, gestation, life, near-deaths, and death, my environment, as much as my original creator's concept, has shaped me. However, to paraphrase, the roads through my hellish environment were paved with good intentions.

My initial environment was covered with legal thorns rather than the nourishing support offered in the '40s and '50s to my "Golden Age" forefathers. Those regulators who abraded my environment and changed my destiny were meant to control risk; and frankly, I might constitute some risk to my host patient since I am implantable and electronically powered. Far more important, however, I dedicate my whole existence to reducing the risk of disease, suffering, and death to my host. Further, it is important to appreciate that my designers, investigators, and users are more directly concerned

Reprinted from *Medical Instrumentation*, Vol. 13, No. 2, March-April 1979. Permission given by: The Association for the Advancement of Medical Instrumentation.

with reducing these risks than are those who created obstacles to my existence because some hidden fault might or might not have lurked far down the road.

Some aspects of my life are shared with famous novel characters. We start out when a happy little spermatozoon (an idea espoused by an inventor) finds an opportunistic ovum (willing manufacturer). Immediately, I am thought to be a future Horatio Alger. However, I am soon discovered living with Pauline (the one with all the Perils). We know frustration, miscarriage, resurrection, orphanage, adoption, more rejection and re-adoption, through a troubled childhood, later to enjoy a degree of success, or more often sent to the gallows by strict liability by a contingency lawyer who prosecutes me over a stray bullet that I did not even know about.

But let's go back to me. Unlike my ancestors, the proof of my safety and efficacy, relative to the disease or condition for which I was created, must be clearly established at greater and greater levels of certainty. There is no question that a reasonable level of certainty and proof of efficacy is desirable, but reason fades as certainty is approached.

It is fair to say that he who regulates science or technology regulates man's ability to defend himself against disease or death.

I have digressed—I have become philosophical.

Many of my litter-mates and I were conceived in the minds of scientists working at a NASA space center, byproducts of another technology. In my case, a physician in Houston saw my possibilities during a discussion at an AAMI meeting in 1975. I was considered to have a great potential as a therapeutic device.

A major obstacle to my development was whether or not someone should, or even could, adopt me as his own because of NASA origin. If I could not be owned, I probably would miscarry and cease to exist. Learned practitioners of law concluded that I could be patented. You've got to have that patent (birth certificate) to prove parentage . . . though bastards are becoming more and more popular. I might have aborted at that point regardless of my value. Fortunately, this did not happen!

A clinical engineer, a physician, and a small company redesigned me and developed a prototype in an environment controlled by FDA good manufacturing practices and regulations promulgated by the Occupational Safety and Health Administration. This was a cross between test-tube conception and cloning. In this environment, I was bench-tested and found to have promise. Thus, I was carefully nurtured by my adoptive parents for the next stage of my life.

A surgeon in Boston was impressed with my potential and asked the parent company if he could order me on an individual basis for a particular patient whose condition was chronic. After another review by the learned practitioners of law, it was concluded that I could be considered as a prescription or *custom device* and be used to save the life of that particular patient in Boston. That is a life sentence as a eunuchoid slave. They chose this life for me because there was a question as to whether or not I could be used in other patients because of the intricacy of regulations pertaining to custom devices. My initial custom use was successful and reaffirmed my promise.

I was a new concept. Thus, more extensive studies and review were necessary to confirm my potential for safe clinical use. Many questions arose: Were my future, services, and market sales worth the burden of more developmental costs of intensive review during

investigation under stringent FDA regulations, plus potential product liability and malpractice insurance? Even when a lot of people saw how well behaved I had been as a custom device (which would have been plenty to guarantee adoption by a nice family, the Manufacturers, during my grandfather's generation), I had to prove that I would never cause my host to have trouble. This was rather like promising it would snow in Minnesota on Christmas Day.

Learned practitioners of Law, Medicine, Engineering, Government, and the Health Care Professions concluded that my potential warranted further review and expense. They extracted an investigational device exemption from the Food and Drug Administration, which required one review by an institutional review board and another by the Food and Drug Administration.

My designers had to provide information and support covering my intended use; my important components, ingredients, and properties; description of principle of operations; anticipated changes that might occur during investigation; and manufacturing conditions available to assure quality control. We got uptight at that point because as a boy in kindergarten I really didn't know the details of my future, much less the use of my Ph.D. thesis! However, the people who provided the ovum and sperm trusted me and persisted. Data available from prior investigations supported my continued development. When the regulators requested more information about my future, my manufacturer went to the old lady across the tracks who read palms.

It was difficult to get informed patient consent" because of the unique condition for which I was prescribed and alternative therapeutic approaches that might be available. When one new patient was presented with all possible alternatives and all possible hazards—information required by law—this very needy patient went all funny in the head and thought he was a guinea pig sleeping in an electric chair, naked, at Yankee Stadium. The scare this caused was nearly my undoing. But a nice cleaning woman said to the patient, "Say yes, they're a doin' the best they can." So the patient said yes on *her* recommendation.

The investigation process required a period of approximately 2 years. Because of the type of device I am, I was subject to the highest level of regulation and potential liability assessment, perhaps rightfully so. I should only be used when I am ready, for I do create some risks to the host patient—of course, not as many as my host's disease, which may soon kill him.

I shall not describe the reams of data that were required before I was cleared for investigational use, nor the safeguards imposed on that investigation. Neither shall I presume to say that they were unnecessarily burdensome. They were a part of my development. And experience is indeed the best teacher.

After 3 years of investigation, enough data were accumulated to support a premarket clearance application to the FDA. This process took another 2 years with extensive review and amendment to the application.

During the process of the premarket clearance application, a standard was written for regulatory purposes. The panel reviewing my application had to determine what effect the standard had on my application. In this particular instance, it had a favorable impact in that the amount of premarket clearance data required was reduced because I conformed to all applicable standards.

Until my clearance by the FDA, my use was still relatively limited. Despite my

potential benefits, the risk of my use had to be clearly known and established . . . as it should be. But it hurt me to think of those patients who would not benefit from my existence.

Finally, I was approved for restricted use, which meant that certain users could use me in appropriate environments.

During my first year of use, I had some problems, I did not have a design defect but unfortunately, the FDA felt my labeling was inadequate for those users who were not familiar with my applications. This is like Billy Martin refusing to put an amnesia victim in the batting order, when a look in his billfold would have identified Reggie Jackson.

At this point, the FDA had several regulatory alternatives: recall, repair, refund, or notify the users. In my case, the availability of further information solved most of the problems.

During the time I was undergoing various regulatory clearances, my sponsors became concerned that I would be obsolete before I reached the marketplace. During the years of regulatory clearance, my sponsors discovered improvements that could be made. They were faced with the question of whether or not they should add to the burden of the regulatory clearance process by requesting clearance of improvements they thought could be made. This created quite a dilemma because of the cost of other factors involved. You know again it's like "Reggie." If you take too much time, he gets very old and he ages without coaching and batting practice. Then he isn't likely to be much good when you finally look at the picture and name on his driver's license.

Even when I scaled the walls of the full-scale marketing process, I had to surmount more obstacles. At each stage, I had to be reviewed by state health planning agencies to determine whether or not my cost was justified. This can be an extremely political process conducted by people who may not know about me or about the illness I correct. Fortunately, I was in the clear in most instances (cleared because I posed no possible future threat to anyone who said yes).

It saddens me to note that during my initial use, the Medicare/Medicaid people felt that I was an investigational device and so did not clear me for cost reimbursement. Recipients of Medicare or Medicaid, even though they need me most, are often poor or old and easily neglected.

My sponsors also ran up against the Environmental Protection Agency when that Agency proposed banning the sterilizing agent which was most effective in making me available for continued use. After repeated communications from the health care professions, like AAMI, the Food and Drug Administration, my sponsors, and other groups, the EPA reconsidered their action.

At this point, the Bureau of Radiological Health and the Nuclear Regulatory Commission got into the act and concluded that the amount of radiation I emitted created health and safety problems. After a year of communications with that Bureau, it was determined that maintaining the status quo would allow the greatest benefit at the least cost to society. After that costly delay to my parents and a few more painful patient deaths by omission, I was cleared again.

As I traveled across my own country doing my best for sick people, I found to my further sorrow that certain counties and cities also have their own local clearance requirements. For example, the state of California has its own drug and device laws. And

yes, certain labeling changes were required to meet local and state requirements. So I complied and was again on my way.

I had the same potential benefits for patients around the world that I had for those in the United States. My sponsors found that to export me they had to comply with certain export requirements under the Medical Device Amendments of 1976. These included approval by the importing country and an indication of compliance with premarket clearance and standards requirements. Once it was established that these requirements were met, I went abroad.

Meanwhile, back at the FCC ranch, learned legal minds were concluding that certain aspects of my performance could cause telemetry interference with emergency medical services and, as a result, I could be in violation of FCC requirements. After 6 months of sensitive negotiations, it was concluded that I was a noninterfering device. Once again I had survived.

In recent months, the Federal Trade Commission has undertaken extensive review of my labeling. As a matter of fact, I have almost forgotten my name. (There is a concern by the FTC that certain segments of the population should have a 90-day trial period before my purchase is considered final. This is a complicated process since I am an implantable device.) Once again, after several months of sensitive negotiations by learned legal counsel, my labeling and warranty requirements were finalized.

Today, my sponsors concluded that the number of lives I can save no longer warrants the cost of regulation and liability. I have been withdrawn from the market . . .

*(signed posthumously for Joe)*

## Epilogue

*Some have said our country's course is all too much like the Roman Empire. Even some of the symptoms predicting its fall are being suffered here. So, in considering my epitaph, I think of the concern of the Roman soldiers who followed Caesar, leaving their wives behind. So, they hired guards for their wives . . . but who would protect them from their protectors? Thus my epitaph:*

***“Quis, Custodiet Ipsos Custodes?”***

[Juvenal]

P.S. Joe wishes to express his appreciation for this opportunity to tell his sad story—first, to Michael J. Miller, J.D., who as a learned lawyer let him tell it as it is. Also, he thanks Dwight E. Harken, M.D., LMSSA (London). The second degree indicates that he is fully licensed by the Worshipful Society of Apothecaries in Medicine, Surgery and Midwifery. We surely used his midwifery in this birth.