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How We Are Regulating Ourselves Out of Business

By Dane Miller

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The Congress of the United States has focused a great deal of its attention on the Food and Drug Administration (FDA) for the past five years. During this period, congressional oversight committees have meddled with the agency's operations to such an extent that the FDA is currently incapable of giving approval to the release of new medical devices into the marketplace. These devices at my company, Biomet, include such things as hip and knee replacements, bone screws, and bone healing products. In fact, the FDA has become such an impediment to the introduction of new devices in the United States that most new or improved devices are available to the rest of the world more than a year in advance of the U.S.

I am in a position to see the dangerous, albeit often hidden, medical consequences of this. I have worked in the field of orthopedic research and product development for nearly twenty-five years, the last sixteen of which I have served as President and CEO of Biomet, Inc., after co-founding the company in 1978. During this time period I have seen America's manufacturers increasingly distracted by the regulatory process as a result of inaccurate tabloid reporting and political sensationalism. This has forced the U.S. Food and Drug Administration and other regulatory organizations to divert from good, sound regulatory practice to a crisis response based on these pressures. As a result, today's manufacturers of medical devices have been forced to spend more money and effort on regulatory approval and compliance with little or no improvement in the safety and efficacy of our products.

Having the Opposite Effect. Legislation to improve the situation has not been effective. In 1990, the Safe Medical Devices Act (SMDA) was passed into law. Industry supported the SMDA because it was intended to get devices into the marketplace in a timely manner. SMDA places more emphasis on postmarket monitoring of devices and less emphasis on premarket requirements. Unfortunately, SMDA has had the opposite effect. SMDA significantly increased FDA's workload but gave no extra resources to handle that increase. Congress merely pressured the agency to step up enforcement activities, and FDA resources were directed toward compliance activities at the expense of new device approvals.

At the beginning of 1993, Congress pressured the FDA into making organizational changes to improve its efficiency and reduce the backlog of product submissions. The FDA recently released the results of an internal survey given to the staff of the Center for Devices and Radiological Health asking whether those organizational changes have improved their efficiency and effectiveness. The Office of Device Evaluation, which is responsible for premarket reviews, had the highest negative response rate at 80 percent. Only 8 percent thought there had been improvement.

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In our experience, congressional interference into the activities of the FDA has had a negative impact on the agency, on the medical device industry, and consequently on the patient. Medical device research and development is increasingly moving overseas to avoid the ever-increasing regulatory burdens in the United States. And the manufacture of devices sold in the international marketplace is moving overseas to avoid the delays associated with FDA export clearances.

In summary, the way in which the FDA carries out the tasks assigned to it by Congress is directly related to the interference and pressure placed on the agency by the Congress. During the past three years, Congress has devastated the FDA, and the industry it regulates, by using the agency as a media and publicity ploy. For example, the public congressional hearings on the "Silicone Breast Implant Crisis" is one example of a grossly exaggerated and oversensationalized issue driven by political gamesmanship. With the FDA's Office of Device Evaluation's premarket review activities in a state of virtual gridlock, new and improved devices are not being made available to physicians and their patients. U.S. companies are discouraged from operating in the U.S. marketplace, but are inclined to supply the international market with medical devices made by foreign subsidiaries.

Let me give you a few specific examples of the frustrations we as an industry face as we deal with the FDA on a daily basis.

My first example concerns the FDA's approval for marketing of a specific hip implant developed at Biomet for patients who needed replacement of a failed total hip.

The FDA has taken more than a year (now typical) to respond to a 510(k) premarket notification for a modular calcar hip stem. A 510(k) premarket notification is *supposed* to be a simplified approval process in products which are similar in design and function to others currently being produced and sold and with a proven clinical track record. The device is a hip prosthesis used for revision surgery; in other words, it is an implant designed for use in a patient whose previously implanted total hip had not functioned properly and required replacement. The hip stem is part of the Mallory/Head Modular Hip System previously cleared for general marketing by the FDA.

The 510(k) was submitted on October 30, 1992, and the FDA's first reply was received November 18, 1993. In their response, the FDA gave us 30 days to complete a fatigue test of 5 stems to 10 million cycles and submit the results. Not only is this an unreasonably short response time in light of the FDA taking more than a year to respond to the original filing, but it is impossible to complete this amount of testing, analyze the data, and prepare a report in such a short time period. If it takes us longer than 30 days to provide the FDA with additional information, the FDA may consider the 510(k) notification to be withdrawn. Once a submission is considered withdrawn, the entire 510(k) must be resubmitted as if it were a new submission. The FDA will then give the submission a fresh date of receipt, and place it at the end of the backlog queue. Our request for an extension of response time is still awaiting action with the FDA and the status of this request is unknown at present.

The second example concerns the folly of FDA policy for solving the backlog problem.

When the government wants to help make things better for you, beware. Congress enacted the SMDA with the intention of helping manufacturers get new devices cleared to market in a more timely manner. Emphasis was to be shifted from premarket requirements and placed instead on postmarket evaluation of devices through an expanded Mandatory Device Reporting (MDR) program. In other words, the FDA would simplify and speed up the approval process and industry would provide more feedback about such approved prod-

ucts after marketing began. As is often the case when regulatory programs are reformed, the intentions are commendable, but the result is opposite of the intent. Here is what actually happened.

Industry complied with the new postmarket reporting requirements, the FDA shifted some of its resources away from the 510(k) approval process into its new responsibilities for post-market surveillance, and the approval process became slower. The Division of General and Restorative Devices now has approximately 2,500 original 510(k) submissions, both under review and/or backlogged. In our experience with the orthopedic branch of this division, the average total elapsed review time for each of these submissions has increased from 90 days before the enactment of SMDA to more than one year today. The backlog problem is so conspicuous that the FDA has been criticized by everyone—the Congress, industry, the news media, the OMB, the Inspector General's Office, and by its own employees.

In spite of the backlog, FDA's Office of Compliance sent a letter in May 1993 to manufacturers of endoscopy equipment mandating the submission of 510(k) premarket notifications for endoscopy accessories. Most of these accessories are low-risk Class I devices, such as orthopedic hand instruments which have been otherwise exempted from premarket notification requirements. One must ponder whether some of the examples of accessories provided in the letter by the FDA (i.e. battery packs, lights, cameras, film, petroleum jelly, etc.) are in fact medical devices.

FDA explained the rationale for its new position as follows. An endoscope is a Class II (special controls) or medium risk device. The FDA now deems that any accessory used with an endoscope is also a Class II device, regardless of its original classification. Since all Class II devices are subject to 510(k) premarket notification requirements, 510(k) submissions must be made for all endoscopy accessories.

Many of these accessories are orthopedic hand instruments which were originally classified by regulation. It is questionable whether the FDA has authority to reclassify them simply by mailing a form letter.

This imprudent policy, which was launched with objectionable timing, will add a few hundred 510(k) submissions for insignificant risk accessories to the already burgeoning backlog.

The third example concerns the FDA policies for clinical studies.

Because of the influx of management personnel into the Center for Devices and Radiological Health from FDA's Center For Drug Evaluation, clinical investigations are being taken to a new level of scientific perfection. Whenever possible, clinical studies for medical devices are to be conducted using randomized, concurrent controls. However for medical device studies, the use of randomized, concurrent controls is unnecessary and impractical. For orthopedic implants, for example, we cannot find any surgeon willing to participate in such a study, nor apparently can other manufacturers. This is partly due to FDA's insistence that the control used can only be an FDA-approved device or procedure. The problem is that surgeons consider these to be obsolete and do not want to use them.

The result is that many new and beneficial devices will not be available to patients. Clinicians are choosing not to participate in a clinical investigation if they must compromise medical care and ethics by using a randomized control procedure which they feel is not in the best interest of their patients.

The use of a placebo in a drug study is quite different from surgically implanting a device permanently into a patient. Surgeons simply will not implant an outdated device into their patients, or use surgical procedures they believe are inferior, just so that the FDA can use the results to justify a safety or efficacy decision.

MDDI Reports - The Gray Sheet is a well-known medical device industry news publication, which in its October 11, 1993, issue provides a chart of the number of device applications under review in each division at the FDA as of August 1993. The quantity of original 510(k) submissions under review or backlogged in the Division of General and Restorative Devices is 2,495. However, there are only 3 original investigational device exemptions (IDEs) under review in the Division of General and Restorative Devices. IDEs are the "long form" of product approval through the FDA where significant questions of safety and efficacy must be answered by conducting and reporting on the results of long-term pre-clinical and clinical studies. Two of those submissions were made by Biomet. In total, *The Gray Sheet* reports only 20 original IDEs under review among all five divisions covering all medical devices. Thus, it seems apparent that the medical device industry has shifted away from truly innovative new product development requiring clinical studies and the "long form" IDE approval process toward evolutionary "short form" approval products.

Along with the reduction of clinical studies is the reduction of truly new devices and technology. FDA policies are creating a climate in which the development and clinical evaluation of truly new concepts is simply no longer feasible in the United States.

For each clinical investigation conducted under an IDE, we must submit an annual report to the FDA. The annual report summarizes, among other things, the number of patients evaluated at each follow-up interval (6 months, 1 year, 2 years, etc.) compared with the theoretical possible follow-up (all patients due at that time interval). The FDA requires that we maintain an 85 percent follow-up rate for each follow-up interval.

One particular clinical study had a slow start due to a delay in the availability of the device. Consequently, our first annual report involved only three patients, one of whom had moved to a new state and was lost to the follow-up. The FDA found the annual report deficient and not acceptable because we had only a 67 percent follow-up rate (2 of 3 patients). Before the next annual report, we made sure we had at least four more patients (6 of 7 patients for an 85.7 percent follow-up rate).

According to the FDA, there are only two reasons that a patient can be withdrawn from the study and considered lost to a follow-up—death or product failure and implant revision. All other possible reasons for a patient being lost, including cases where the patient refuses to return for an examination unless a problem arises, or the patient has moved to another state, are considered failures by the FDA.

The FDA considers clinical studies which fall below the acceptable 85 percent follow-up rate at each follow-up interval to be improperly monitored by the attending physician. Yet, there is no provision in the law to allow us to coerce [provide patients with an incentive (money) to remain] patients into remaining in the study. In fact, FDA regulations state that the informed consent agreement provided to the patient must include a statement that the patient is free to withdraw from the study at any time and for any reason with no bias as to future treatment.

The FDA's attempt to achieve accurate follow-up studies is hampered by the allocation of patients in the sample. For example, in the real world, 85 percent to 90 percent of all total hip and knee joint replacements are performed on patients with noninflammatory degenerative joint disease (such as osteoarthritis, traumatic arthritis, and avascular ne-

crosis). But for our clinical studies, the FDA makes us divide our patient population into four equal diagnostic groups, only one of which is for noninflammatory degenerative joint disease. In other words, if the patient sample size is 200 cases, only 50 cases can be performed on patients with noninflammatory degenerative joint disease. Fifty cases are allotted for rheumatoid arthritis, 50 cases for failed prostheses, and 50 cases for functional deformity (e.g. congenital hip dysplasia).

In other words, 150 cases (or 75 percent) of the total sample size of 200 cases will involve patients with indications observed in only 10 percent to 20 percent of patients in the real world. Conversely, only 50 cases of 200 cases (25 percent) will be performed for the indication observed in 80 percent to 90 percent of patients in the real world.

This is FDA's "equal opportunity" program for diseases, and fails to recognize the realities of health care.

My fourth example of the frustrations involved in complying with FDA requirements concerns the U.S. Mail.

All submissions sent to the FDA must be mailed to the FDA's Document Mail Center in Rockville, Maryland. Last year the Document Mail Center sent over 600 submissions to the wrong divisions to be reviewed. This added 30 to 45 days of review time to these submissions just to redirect them to the proper divisions. The situation is significant enough that the FDA is considering contracting this function to a private business.

The fifth example concerns the FDA's determination in effect to require other countries to accept our regulation, if they want our products.

If our firm exports a medical device which is not yet approved in the United States to a foreign country, first we must get written approval from that foreign government. But, next we must submit the approval letter from the foreign government to the FDA to get FDA's written approval. Then, if the device is labeled properly and we have not yet reached retirement age, we can export the device to that country.

All this red tape is an unnecessary waste of resources which is of absolutely no benefit to the public health. Usually, foreign governments set up import barriers to help protect their domestic industries from foreign competition. In this instance, it is the U.S. government which has set up an export barrier which impedes U.S. industry from exporting medical devices.

For example, Biomet's U.S. facilities are registered with the United Kingdom's Department of Health. Our plant facilities are subjected to an intense on-site inspection by an audit team from the U.K. Department of Health approximately every 18 months. We have spent several thousand dollars to assure that our U.S. facilities comply with the regulatory scheme of the United Kingdom.

Nothing could be more inconsequential to the U.S. public health than to get FDA's written permission to ship a device to the U.K. The FDA could be using these resources to reduce the backlog of premarket submissions, which is probably the reason the device has not yet been approved in the U.S. This regulation discourages the export of U.S. medical devices into foreign markets, and encourages the relocation of their manufacturing operations to overseas facilities.

Since Biomet, as well as many other device manufacturers, own manufacturing facilities in the U.K. and Europe, we have been influenced to manufacture certain products overseas to avoid the FDA regulatory hassle. These were U.S. jobs which the U.K. and Europe were pleased to accept.

My last example shows the absurd ways in which the FDA can "solve" a problem.

Based on a series of articles in the *Minneapolis Star Tribune* concerning deaths and injuries associated with the use of patient restraints, the FDA decided to investigate its Mandatory Device Reporting (MDR) files. The FDA found a total of 41 deaths and 16 injuries associated with the use of patient restraints of all types including safety vests, hand mitts, lap and wheelchair belts, body holders, straitjackets, protective nets, wristlets, and anklets. The agency found that these devices are applied to very elderly, severely demented, or extremely ill patients who require protective restraints for needed medical care. The FDA also determined that the deaths and injuries were caused by improper application of the device, or improper monitoring of the patients. There was no indication that the devices were designed or manufactured improperly.

One would anticipate that faced with this, the FDA would launch a public awareness program to warn the users of the dangers associated with improper use and monitoring of patients in restraints.

Instead, the FDA's first action to deal with this user-related problem was to withdraw the exemption for patient restraints from the premarket notification 510(k) and good manufacturing practices (GMP) regulations. This means that companies currently distributing patient restraints must submit 510(k) premarket notifications to continue. In addition, good manufacturing practices (GMP) regulations now apply. Patient restraints are manufactured in sewing facilities which make low-risk orthopedic soft goods, such as arm slings. Orthopedic soft goods are exempt from GMP regulations. Consequently, patient restraints will now require special handling to comply with regulations which are not applicable to any other devices made in that facility.

The FDA's second unfathomable action was to make manufacturers attach permanently affixed labels to the restraints with directions for use, warnings, and precautions in several languages, and a series of drawings which depict the proper application to the patient. The required drawings must also depict the proper methods for anchoring the straps to the bed or chair. The labels should withstand repeated laundering over the lifetime of the device. And the restraints should be permanently labeled so users know which is the front and the back.

In the 17 years that Biomet has sold patient restraints, we have not had a single reported user complaint. After evaluating these new requirements, however, we determined that the added cost of compliance was not worth remaining in the patient restraint market. Consequently, we discontinued the manufacture and sale of patient restraints. Our excellent product is no longer available to those who need it.

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