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From: Ronald E. Eames  
President and Managing Director

## Comments on FDA proposed Regulations for Service of Single-Use Medical Devices

I have read the proposed "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals", Docket No. 00D-0053. Before I make comments I would like to establish a few facts that will place my comments into better perspective. I realize that this document is only for the purposes of establishing and identifying the current thinking on the public policy issue represented by the servicing of disposable medical devices. Nevertheless, this kind of policy statement, along with public comments and suggestions begin to "take on a life of its own", unless stopped or re-channeled in a more positive direction at the very earliest possible moment.

I have been in the disposable and single-use Medical Device Service Industry since 1993. My company is voluntarily certified to ISO 9002:1994 Quality Assurance Standards by Underwriters Laboratories, Inc.® for the following scope of registration "The provision of servicing, packaging, and sterilization of medical instruments". We are a UL® registered company, File No. A8283. As an ISO certified and registered company, we voluntarily submit to multiple inspections and quality audits each year in order to retain our current status. We are inspected at our own expense and our commitment to quality must be real and verifiable at all times in order to qualify. I am including a copy of our most current certification with these comments.

I wish to make it clear, having examined the practices of most of the companies involved in this industry that the word "reprocessing" is a misnomer and inaccurate. I expect the inaccurate language is a deliberate regrettable and disingenuous attempt to circumvent the clear statutory restrictions placed upon the FDA regarding any effort by this agency to regulate the "servicing of medical devices". I do not ascribe this inaccuracy to any single individual; rather it could have initially began as a convenient way of describing numerous semi-related activities with one designation. Once legal enforcement problems were reviewed, the misnomer became an official part of FDA intentions to re-define service activity in ways not supported by legislative intent.

I also expect the original error was compounded and helped along by a number of other vested interests. In fact, a portion of the blame for perpetuating this inaccurate designation can even be placed on the various lobbying organizations established to promote the interests of the disposable and single-use Medical Device Service Industry. I recall numerous instances where influential individuals from those organizations referred to the servicing of medical devices as "reprocessing" them. It is one of the reasons I have avoided becoming involved in their efforts.

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Regardless of the origination of the inaccuracy, the enabling legislation only gave statutory authorization to the FDA to regulate the “First Introduction into Commerce” of medical devices. In that same legislation, the term “Reprocessing” identifies a specific activity, which does not include servicing of those “first introduced” medical devices, either internally or through third-party contract. We are a service industry for Healthcare Providers. That is who we in this industry really are, and what we really do. This is the activity the guidance document addresses. It is false and misleading to state otherwise.

Virtually all companies in the industry whose activities are described in this guidance document receive instruments whose title remains in the hands of the healthcare providers that purchased them originally. These instruments are cleaned, serviced, packaged, (in some cases, sterilized) and sent back to the rightful owners for reuse. They are not reprocessed for introduction into commerce. They have already been “first introduced into commerce”.

Seven years ago, I was the creator and designer of the first service program for properly servicing numerous types of used disposable and “single-use” devices which had not been (until that time) viewed as commercially viable candidates for service. Five years ago, as President of a company called “Applied Medical Technologies, Inc.” my program was inspected by the Food and Drug Administration for compliance with good manufacturing practices and standards (GMP). This inspection occurred in April of 1995 and my program passed that inspection. Until that inspection took place, it appeared to be accepted wisdom that “used” disposable and single-use medical devices were either not worth servicing in order to extend their useful life, or were unable to be serviced in compliance with GMP.

As President of Medical Device Services, Inc., it is my firm conviction that participation by the FDA to establish minimum standards of conduct is essential to the health of the Medical Device Service Industry to which I belong. I believe FDA guidance and involvement is absolutely imperative for our long-term success. I have had substantial influence in creating this new industry and I want it to remain healthy. Having stated my support of FDA participation in clear and concise language, it is with real regret that I take the following position:

“The draft guidance document, proposed “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals”, Docket No. 00D-0053, presented by the Food and Drug Administration is ill-conceived and does not best serve the public interest or public protection. The public policy and safety issue represented by the servicing of disposable and single-use medical devices can be resolved without the necessity for further Federal regulation or legislation. The FDA, in this Guidance Draft, has failed to take into account the powerful mechanisms already in the marketplace that can be utilized by the FDA with little or no cost to the taxpayer. These mechanisms can cause the Medical Device Service Industry to police itself to eliminate any perceived public safety issue resulting from the service of these types of medical devices”

I also wish to make something else very clear, now that I have stated my position. I have thoroughly reviewed the proposed enforcement priorities. With very few exceptions, none of the proposed requirements even affect my business or its current operation. Almost all the instruments we service are already exempt or already have been subject to substantial clinical trials showing safety. Those remaining instruments listed are ones we would not service without far more substantial clinical data than suggested in the guidance as a minimum requirement. I am not adamantly opposed to the current direction of FDA thinking because it materially affects my company's economic well-being. FDA thinking or proposals simply don't affect the economics of my company at this time. My "Ox" is not being gored with this proposal.

The reason I am adamantly opposed to FDA current thinking is because on a long-term basis, it will be severely detrimental to the industry I helped form. It is simply the wrong way to address the problems within this industry. It is overly burdensome and yet not sufficiently restrictive in certain ways so as to actually protect the public. We will, therefore, all have to bear the brunt of adverse publicity when something does go wrong.

If we take the regulatory path laid out in the Draft Guidance paper, experience and practicality tells me it will be almost impossible to restore the regulatory effort in this industry to the right path or direction. The proper direction is self-regulation like any other healthcare provider service. Further, that self-regulation must be equivalent to current healthcare provider Quality Assurance standards. The Draft Guidance doesn't go far enough, and yet goes too far. The FDA is creating a paradox for miscreants to exploit.

It was of material benefit for my service program to be inspected and evaluated by the Food and Drug Administration in 1995. At the time the inspection took place, I welcomed the presence of the field agent and the experience he represented. The suggestions made at the time of the inspection were helpful and of real assistance. In fact, as I have already made plain, it is my absolute belief that this new disposable and single-use Medical Device Service Industry (which burgeoned shortly after that inspection) must always have some form of active participation and involvement by the Food and Drug Administration to assure our industry conformance to high standards of conduct. The only real question in my mind is how and in what way?

I am also very aware of the need for a regimented well-defined quality assurance program geared to protect the safety of the public when operating as a Medical Device Service Company. After I left Applied Medical Technologies, Inc., the program I created was altered, cheapened and subverted by unscrupulous individuals who apparently attempted to maximize profits at the expense of safety. At the next inspection, the Food and Drug Administration issued notices of non-compliance with GMP and eventually issued a Warning Letter to that company for failure to return to the high standards previously set. That company is no longer in business. The FDA should realize from this example that adverse publicity can be a very powerful tool for correcting any deficiencies in this industry.

There are specific distinctions and delineations between manufacturers of Medical Devices and Healthcare Providers in the authorizing statutes granting powers to the FDA to regulate the "First Introduction Into Commerce" of any medical device. As Service Companies, we are ancillary to Healthcare Providers. We are not manufacturers nor are we subject to "First Introduction"

restrictions that apply to manufacturers. We have been placed in the position of healthcare provider support rather than in the business of manufacturing instruments, which then must be first introduced into commerce.

While the FDA appears to have interpreted the authorizing statutes in an extremely broad way, the fact of the matter is that there is no appreciable distinction in law between reusable medical devices and disposable medical devices. The statutes quoted by the FDA as empowering them to regulate this activity only apply if we are “manufacturers” or “reprocessors” as those terms and activities are defined in the authorizing legislation. In reality, virtually all mechanical medical devices are disposable once they have exceeded their useful life unless they are serviced to extend that useful life. Even then servicing only extends the useful life of any instrument to a limited degree. For example, even a pair of “reusable” scissors can only be sharpened a certain number of times before it is discarded. Further, that pair of scissors must be serviced in a substantial way between uses. In a way, almost all medical devices are single-use unless serviced.

Since this is the case, there are two key issues that have not been adequately addressed by the FDA in their “Draft Guidance” document.

**First:** What is the Public Policy Issue and accompanying proof, which necessitates FDA involvement in a healthcare provider aftermarket activity not directly covered by any statutory authority the FDA was given to regulate the “First Introduction into Commerce” of medical devices?

**Second:** What is the specific overriding Public Policy Interest that would allow the FDA to ignore the will of congress and simply circumvent the clear concise language written into the authorizing statutes when those same statutes prohibit the FDA from regulating the servicing of medical devices which are not materially altered when serviced?

I expect that, having stated the two issues in the manner in which I did, a reader of these comments would have difficulty is reconciling my sincere request for FDA participation in our industry with the two statements hereinabove. For those who do not believe that the FDA is prohibited from regulating the servicing of medical devices already “first introduced” into commerce, I would suggest a more thorough reading of Food and Drug Administration Enabling Legislation (and accompanying legislative history and comments) to regulate medical devices. As long as a device is not materially altered from its original form/function, the FDA is precluded from regulating service activity except in the most general way. There is no ambiguity in the statutory language. Even that general way requires a very liberal interpretation of the Act.

How then, should the Food and Drug Administration become involved in an activity that appears excluded by statute? The answer is simple, straightforward, logical, and without the need for further agency regulations (it may be that these very qualities may be the major stumbling blocks to acceptance. It may be difficult for everyone now involved to believe that a simple answer exists to what has been overblown into a very complex issue). As a leader in this industry, my experience is that the issue, and the perceived problems are not that complex at all.

The issue and the attendant potential for misconduct resulting in possible reduced public safety can be defined quite simply. Hospitals, surgical centers, and other healthcare providers want to extend their savings realized on “reusable” medical devices to those medical devices also described as “disposable” and/or “single-use”. The demand to save and reduce waste and losses incurred by healthcare providers is a strong public policy concern. The servicing of disposable instruments to extend their useful life promotes that public policy. That is the issue in a nutshell. The problem that presents itself from that issue becomes equally simple to define: Is the practice of servicing disposable or “single-use” medical devices safe? The power of the FDA to guarantee an affirmative answer to that question is already in the hands of the FDA. Under current law, the servicing of any instrument may not materially alter its form or affect its function.

The FDA has repeatedly acknowledged that an act of cleaning, sharpening, repackaging, and sterilizing a medical device does not materially alter its form/function per se. Since that is so, the real question then evolves into the following... “Are there devices where the simple act of using a device so fundamentally alters its form/function that the act of servicing may no longer restore it to its intended form/function?”

Obviously, in a number of instances the answer to the above question is also “yes”. Those instruments alone should be the subject of concern by the FDA and the object of any legitimate action proposed or taken. The FDA cannot formulate “blanket” regulatory requirements on groups of medical devices already first introduced into commerce and expect to survive a challenge. Any restrictive requirement must be specific and supported by data.

I support any public disclosure requirement that would give the FDA more data upon which to act. I support any effort of the FDA to require Medical Device Service Companies to notify the FDA as to what instruments are being serviced. I support any effort of the FDA to require Medical Device Service Companies to notify the FDA of any material complaint from any healthcare provider regarding a serviced medical device. I certainly support any effort of the FDA to obtain accurate and valuable data regarding the activities of our industry, including any data that would aid in cost/benefit or use/degradation analyses.

The FDA receives Medical Device Reports (MDR) on cases where a patient has been materially harmed through the malfunction of medical devices. These MDR’s are the lynchpin of any effort to legitimately protect and guarantee that the service of any instrument, whether “reusable” “disposable” or “single-use” is safe. How can this information and other data encourage self-regulation in the Medical Device Service Industry? There is an example already in place.

In general ways and means, Hospitals and surgical centers routinely regulate themselves without appreciable interference from the Food and Drug Administration. JCAHO or “Joint Commission” inspections and other ‘inside-industry’ oversight structures guarantee at least a minimum level of professional activity that is the envy of the world for the quality of care given to patients. Various professional advisory organizations establish “recommendations” that Healthcare Providers incorporate to maintain their professional status.

Through their central processing/sterilization systems, hospitals and surgical centers consistently service hundreds of thousands of instruments without the need for FDA direct involvement in the

standards to which those instruments must conform. It is this same type of self-regulating activity that the Food and Drug Administration must promote most vigorously within our Medical Device Service Industry. We must be held to the same kinds of standards that AORN and AAMI recommend for “reusable” devices, especially in the area of cleanliness.

Why? Because our new industry is part of the Healthcare Provider system but we are not reviewed or inspected by JCAHO. We act as ancillaries to Central Processing but there are few, if any recommendations are available to us from advisory organizations such as the Association of Perioperative Registered Nurses (AORN) or the Association for the Advancement of Medical Instrumentation (AAMI), as they pertain to disposable and single-use devices.

There is a rational explanation for this silence. The FDA is the entity into which adverse information must flow. These private organizations do not have the extensive database that is in the hands of the FDA regarding any misuse or failure of these types of instruments, new, or reused. Furthermore, hospitals are simply not set up to service the vast majority of these types of disposable or single-use instruments on a cost-effective basis, nor are their personnel specifically trained to service the instruments effectively. Therefore, for the most part, they don't; we do, and those of us who have gone the extra mile and voluntarily certified to a recognized International QA standard do our job very well without government intervention.

How then, can the FDA act as a Leader in promoting self-regulation of the Medical Device Service Industry and give guidance to the Medical Profession, which is desperately seeking such guidance? This is where the answer becomes simple again, and therefore suspect to those individuals to whom more regulation is always the solution. There are recognized standards that insure public protection better than the FDA “enforcement priorities” for servicing disposable medical devices generically identified into groups by some arbitrary sort of perceived risk.

To resolve the problem in the most effective way possible, the FDA should issue a Guidance, or Recommendation Report, updated periodically and available (by internet or some other inexpensive and effective means) to all healthcare providers and Medical Device Service Companies. This report would serve the purpose of sharing information regarding the servicing of any used medical device, whether by the healthcare providers themselves or by third-party service companies.

The most important initial recommendation by the FDA would be that any service of any medical device by a third-party, (regardless of its designation as reusable, disposable, or “single-use”), be done in a facility independently certified to a recognized quality assurance standard. This standard would require verification of quality assurance compliance analogous to JCAHO. There is an excellent standard with quality auditing systems already in place. This Quality Assurance standard is Internationally recognized as ISO 9002 for service organizations. In fact, the original purpose of the Global Harmonization Committee was to essentially meld GMP with International Standards for Quality Control.

How better to accomplish self-policing of our industry than through recommendation of certification to an internationally recognized standard? What recognized quality standards guarantee best protection to the public? What standards compare to, and even exceed GMP, the

minimum standard acceptable? Companies certifying to ISO 9002 also must pay for it themselves without taxpayer cost and they must proactively seek compliance at all times in order to retain their status. This is far more effective than relying on the visits of overworked field agents to track down problem facilities, after the problem occurred. That is too late, anyway.

For self-policing to be effective, since our industry falls on the healthcare side of the regulatory equation, the FDA must support and promote the concept that Medical Device Service Companies must be as proactive as the rest of the medical profession by certifying their standards through constant periodic independent quality assurance auditing. Further, the service activities of these companies must be audited and guaranteed by recognized and qualified quality assurance agencies, laboratories, and/or QA Auditors. ISO certification, with registrars and auditors throughout the United States accomplishes this purpose effectively.

In other words, it is as important for a Medical Device Service Company to provide proof of consistent quality as it is for a hospital to pass “Joint Commission” inspection certifying its quality. Having been voluntarily certified to ISO 9002 standards by Underwriters laboratories, Inc.©, I can state with accuracy that the inspection, certification, and registration process is a realistic analog of the “Joint Commission” inspection process.

The added benefit to the FDA of recommending independent certification to a recognized standard by a qualified auditing firm or agency is that FDA field agent time is not wasted in inspections. Medical Device Service Companies must be obligated to police themselves in the same manner as any other healthcare provider. An FDA Guidance or Recommendation Report suggesting this requirement as a minimum standard for third-party service companies would go a long way to cleaning up any perceived shortcoming within the Medical Device Service Industry.

With certification/self-policing activity as the initial recommendation, the foundation is laid for the next simple and effective step in resolving any question regarding the quality and safety of serviced instruments. Starting with a recommendation of independent certification to a recognized standard in place, the FDA can then publish within that Guidance/Recommendation Report, a specific list of medical devices that have been shown to cause material harm when such devices malfunctioned, whether new or reused. That is a legally defensible position showing appropriate concern.

The FDA, as the recipient of MDR's is the only entity that is capable of being the official information conduit to healthcare providers and telling them of concerns with specific devices showing specific harm. That is the kind of information, which must be the guiding force in setting the boundaries of our industry. But enforcement of those boundaries must be in the form of self-policing as healthcare provider “subsystems”, not as if we were manufacturers.

Companies intending to service instruments on the “material harm” or “high risk” list (call it what you will), will have to show their certifying auditors, prospective clients and the FDA through clinical evaluations or other acceptable protocols that their proprietary ways and means of servicing the instruments on the “high risk” list render these instruments safe. After all, the FDA, once a medical device is first introduced into commerce, really has limited statutory authority or reason for getting itself involved in the question of effectiveness. As long as safety is

not an issue, that is a contract matter between the healthcare provider and the third-party servicing company. As long as form defines function, this issue is the same as a dull pair of scissors or an osteotome with a broken tip.

The only medical device exceptions would be where the words ‘safety’ and “effectiveness” are synonymous. Common examples are hemodialysis membranes and various implants. This distinction does not appear to affect the majority of Class I or Class II medical devices but concentrates efforts on insuring that most “used” Class III medical devices are properly serviced for safety. That is a very rational position and the essence of simplicity.

In summary, the Food and Drug Administration really does have an extraordinary opportunity to act as a guiding force to insure public safety regarding the servicing of any medical device, not just single-use devices. While the medical profession as a whole, is highly resistant to being compelled to comply with generic regulations from a governmental source, the real irony is that this very same stubborn and independent medical profession would appreciate and actually utilize any guidance or recommendation paper which

- (1) States in clear and simple language recommending that service companies that offer to service medical devices of any type must be able to prove their quality control system meets a recognized International Quality Assurance Standard of a scope and depth of inspection analogous to the standards already in place for healthcare providers. The current standard that meets this description is ISO 9002 for medical service companies. This proof must be in the form of certification and registration by a recognized quality auditing agency or firm that backs up its quality auditing statement with its reputation.
- (2) Periodically publish and update a specific list of instruments that have been shown to materially harm patients through a malfunction and/or improper service. As a matter of practicality, since product liability insurance coverage is required in our industry by our clientele to service their instruments, any company that would offer to service these high-risk instruments must be able to demonstrate that their service protocols render the instrument safe for use. If the data were submitted to the FDA, the FDA could issue reviews of the material submitted and recommend that no healthcare provider accept service from any company for instruments on the list unless such protocols were submitted and accepted by the FDA as evidence of safety.
- (3) Publish a list of recommended proscribed instruments for which (1) its use alone so materially alters its form/function as to make service impossible, and/or (2) no cleaning and service protocols appear to restore original form/function, and/or (3) which reuse has resulted in the death of a patient.

As a person that probably has the most extensive experience in this disposable medical device service industry, I can assure the Food and Drug Administration that mechanisms to police the Medical Device Service Industry are already in place. We need no additional confusing and burdensome regulation or costly enforcement. It requires wisdom on the part of the FDA rather

than the brute force approach. It requires a perception that the FDA is acting to protect the public interest rather than respond to pressure from medical device manufacturers or contributors in an election year. It requires guidance and leadership rather than ‘knee-jerk’ regulation-response.

Having read and re-read the Draft Guidance paper numerous times, I would not like to be the one responsible for trying to implement the proposals contained therein, especially if my agency were underfunded and understaffed for the tasks already at hand.

I expect that FDA internal staff is not real familiar with actual marketplace pressures that exist to keep the medical healthcare provision system whole, safe, and effective. This is not a failing within the bureaucracy of the FDA. It is, in part, an inevitable result of the FDA having to constantly resolve and deal with the failures within the system rather than its successes. The overall effect within the agency is that there is an understandable bias toward more laws, more regulations, more prohibitions whenever a perceived problem arises, however inaccurate that bias may be.

What the FDA must recognize is sometimes problems require other solutions than just more regulation or governmental interference; just as a boil requires a lancet rather than a sledgehammer. (I suppose in a bureaucratic sense, a sledgehammer would be considered just as effective for a boil. The immediate issue is resolved. Any new complications resulting from the solution may offer more upward mobility with more staff to hire and administrative slots to fill).

Regardless of current FDA thinking, this is what I know...I know from experience of placing my program in more than 450 hospitals and surgical centers over the years, risk management personnel and hospital staff are dedicated to keeping the level of healthcare to patients at its current high level. They will listen to guidance from the FDA if that guidance appears unbiased and based on reliable data or solid information. They live with complex and critical decisions every day. They use every reasonable source of information to help them make those life and death decisions.

With my experience, I assure the FDA in the strongest terms possible, those Hospitals and Surgical Centers interested in servicing disposable and “single-use” medical devices will act upon FDA advice. The one stipulation is that the FDA must exhibit unbiased perception with supporting data as a prerequisite for acceptance. That is the required standard that these people accept in their professional lives. The agency does not realize how much power it has as a guide to stimulate responsible action. The FDA must use that power, and use it wisely. Coercion will be resisted.

The risk managers and OR supervisors in hospitals and surgical centers I have met over the last seven years know that many medical devices are marked “single-use” for no good reason at all. In general they don’t understand why. They also know that many medical devices are marked “single-use” because the original manufacturer is not prepared to accept liability for a medical device that could be reused but only if serviced properly to achieve cost effective savings. That is a reasonable limitation asserted by original equipment manufacturers that anyone may rationally accept. It is precisely for these instruments I have generally devised my service program.

These same bright and dedicated medical people also realize there may exist medical devices marked “single-use” which may be shown to be too fragile, too poorly made for additional use, or simply too dangerous to try to recover, service and reuse. This is where the data provided to the FDA in Medical Device Reports could be put to best use. They want to know and factor that information into their decisions. They will accept advice even regarding in-house practices.

My experience tells me that if the Food and Drug Administration creates the right guidance environment, this industry will police itself and eliminate any perceived misconduct without the need for further FDA official involvement. Medical Device Service Companies willing to meet the requisite standards will thrive and companies acting in an irresponsible manner will terminate because they cannot effectively compete.

No rational healthcare provider will utilize any proscribed services if they wish to avoid liability. No rated insurance company will issue liability protection for companies servicing officially listed dangerous instruments without accompanying protocols proving their safety. No reputable quality assurance inspection registrar or agency will certify companies who fail to comply with industry recommendations from a governmental agency whose job it is to assemble data and report the unbiased results. Therein resides the real power to regulate healthcare provider ancillary activity.

This relatively new Medical Device Service Industry is already providing a marketplace stimulus that has been missing from the disposable and “single-use” market for some time. We are seeing some manufacturing companies lower their disposable instrument price in order to try to make servicing those instruments less cost-effective. We are seeing some companies improve the quality of their instruments. This insures that those instruments can be serviced a number of times for overall improved competitive position relative to other manufacturers. We have even seen some companies admit to healthcare providers that their instruments can be serviced multiple times even though they are marked “single-use”. This admission has improved their position with respect to competitors and has lowered overall costs. All this is for the public good.

I think that the Food and Drug Administration ought to act in a most careful and logical manner before interfering in lawful marketplace activity that is already beginning to lower overall healthcare costs. If a way exists to police an industry within that industry itself, the FDA must utilize that method and evaluate the results before attempting to create new regulations, especially where no clear statutory authority exists. The case for radical public protection policy has not been made at this point. Therefore, regulation would not only be unwise, but arbitrary and capricious. I volunteer my support for any effort toward a rational, logical, internal, common-sense effective way to promote self-policing of this industry.

It is possible for the requisite periodic Guidance or Recommendation Report to be created by a committee appointed to represent all interests involved instead of solely or directly created by the FDA. Such a committee could take the data offered by the FDA and act as the advisory entity similar to AORN, or AAMI, for our own industry. The FDA would appoint the advisory committee or simply participate in it. I would volunteer without compensation to serve on such a committee. I know others of good will have an honest desire to see our industry flourish and operate safely for the public good as well as our own. I feel sure they would be willing to serve,

as well. We simply don't need another layer of regulations which are suspect, and have been "force-fit" to deal with this perceived problem.

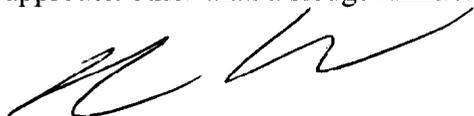
By utilizing market control mechanisms already in place, the FDA won't try to throw this new industry "baby" out with the bathwater. We need real leadership in this new Service Industry and the FDA can be the source, enhance its position and reputation, and resolve the perceived public safety issue raised by potential misconduct.

I believe it would be a major disaster for the Industry I helped create if the FDA were to eventually force such convoluted and twisted regulations upon us. They are neither fish nor fowl. They are a kluge of well-intentioned ideas that do not directly address the issues as defined herein. The proposed enforcement priorities do not satisfy the original manufacturers because their hope is to see all third-party servicing terminated. The practitioners of third-party servicing will object because we are artificially and arbitrarily subjected to regulations that only apply to manufacturers. Companies servicing "reusable" medical devices will object because it establishes precedent to regulate them in ways they never expected when they built their businesses.

Members of Congress will object because they feel it is rather hubristic of an agency to simply ignore direct prohibitive statutory language. In addition, it would require a massive increase in FDA budget to just wade through and process the new paperwork requirements for compliance. Small business organizations will object because it causes an environment wherein only well-established and well-capitalized companies can hope to compete. Healthcare providers will object because the cost of service will increase to take into account the additional regulatory burden. The final insult: with these regulations, the end result may, or may not, be as effective as self-regulation, but they sure will be a whole lot more expensive, both to the taxpayer and to the participating companies. In addition, just the thought of regulating in-house hospital servicing of their own purchased equipment and medical devices will raise a firestorm to no good purpose.

With so many interests objecting, any regulations will eventually end up in court where these regulations will be overturned. Such a decision would open the doors to malefactors to participate in this industry and would undermine any subsequent effort to remedy or self-regulate except through additional legislative authorization. Any legislation further empowering the FDA would be vigorously opposed by numerous special interests already less than enchanted with the agency.

I believe it is the right time to rethink how best to solve any perceived public safety issue raised by third-party servicing of disposable and single-use medical devices. I think it is time to take a new approach other than a sledgehammer. The current approach is actually counterproductive.



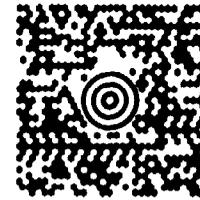
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