COOK GROUP INCORPORATED
750 DANIELS WAY,
P.O. BOX 1608
BLOOMINGTON, IN 47402-1608 U.S.A.
PHONE: 812.331.1025 FAX: 812.331.8990
WWW.COOKGROUP.COM

December 6, 2011

The White House
Office of Science and Technology Policy
Executive Office of the President
725 17th Street, N.W., Room 5228
Washington, D.C. 20502
BIOECONOMY@OSTP.GOV

Re: Request for Information: Building A 21st Century Bioeconomy

Dear Sir or Madam:

We submit these comments on behalf of Cook Group Inc. (Cook). Cook is a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine, and surgery. Cook pioneered the development of products used in the Seldinger technique for angiography, and in techniques for interventional radiology and cardiology. Our products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. Cook sells more than 15,000 different products, which can be purchased in more than 60,000 combinations.

Our company employs about 10,000 people around the world. Eight thousand of those are based in the United States. While 50 percent of our products are sold outside the United States, 85 percent are manufactured in this country.

We commend the President and the Administration for recognizing the importance of the Bioeconomy. The U.S. is the world leader in biotechnology, and we believe it is critical that the nation do everything possible to promote and expand the biotech industry if our nation is to compete economically during the rest of this century and to ensure our citizens have the best available health care.

The medical device industry is an important segment of the bioeconomy. It employs nearly 500,000 people manufacturing products that save or improve the lives of millions of Americans and generates a trade surplus in excess of $5 billion. Salaries in the device industry average $58,000, according to the Department of Commerce. Further, it is an environmentally clean industry. Developing public policies that promote growth in this industry is exactly what our government should be doing as we struggle to emerge from a deep recession.

We welcome the opportunity to provide information addressing specific issues raised in the Request for Information. Before doing so, however, we would like to provide general background information, which we think is urgently important.

While the medical technology industry has been one of the jewels in the American economy, its position as a global leader is eroding. This will undoubtedly affect the ability of Americans to access future break-through medical advancements and the growth of U.S. jobs. A recent study found that in the future, China, India and Brazil will experience the strongest gains in developing next generation lifesaving products. Without changes to U.S. policies, these gains will move capital, jobs, and research away from the U.S. and toward these growing markets. (Source: "Medical Technology Innovation Scorecard: The Race for Global Leadership," PwC, January 2011).

There are several policies that are driving American medical device companies to seek clinical data and manufacture and launch new products outside of the United States.

1) Imposition of a new, 2.3% excise tax on the sale of medical devices. This tax is levied on domestic sales, not profits. For a typical, larger medical device manufacturer, the tax will be a burden of 15-20% on earnings (in addition to federal and state corporate taxes). To smaller start-up companies not yet making a profit, it will be an additional cost that must be financed. While the tax will also be assessed on imported products, profits from those products will be subject to a much lower corporate rate in foreign countries. This increases pressures to move production abroad.

2) An FDA regulatory environment that is painfully slow and risk averse despite strong safety records. In stark contrast, the European system is more transparent, timely and predictable.

3) A U.S. corporate tax structure that is one of the highest in the world, second only to Japan.

4) Cynicism regarding the proper roles of health professionals, academia, government and industry and the relationships among these important stakeholders.

All of these policies must be addressed to reverse the trends faced in developing new medical technology. We recognize that the central focus of the Request for Information is narrower, but we hope that the Office will include all important policies in its "Bioeconomy Blueprint."

In response to question 15 of the Request for Information regarding improvements in the regulatory processes for medical devices, we are attaching a list of specific suggestions for changes that FDA could make to improve its performance. Although the list is lengthy, we

believe that all of the recommendations are important, not only to the Bioeconomy, but to patient health care as well. We have been communicating with FDA on a regular basis concerning these suggestions and believe the Office of Science and Technology Policy should also be aware of them.

In reviewing this list, it is important to keep in mind the unique nature of the process in which medical devices are developed, which is quite different from that of pharmaceuticals. The device development process is for the most part evolutionary, with incremental changes, rather than revolutionary. When a device is introduced doctors use it. Some will come up with ideas to modify the device in minor ways to improve its performance or to allow them to use it for slightly different anatomy or indications. These changes are made and this in turn leads to more ideas from physicians that lead to more changes and so on. This incremental and collaborative process has led to steady improvements in technology, which over an amazingly short period of time, have led to a revolution in the practice of medicine. The keys to this evolutionary approach have been close collaboration between medical device users (physicians) and medical device developers (industry) and a medical device regulatory structure that recognizes the value of building new medical devices upon the foundation of those that are on the market and have a solid history of safe and effective use.

Further, it is important to recognize that levels of regulation should reflect risk associated with a specific device and that the system must be flexible to changes in risk that occur as we gain experience with a technology. There are many questions that need to be answered with a new medical treatment using novel technology, but as it is used by thousands of physicians to help their patients, there are fewer and fewer questions that arise. It is wasteful to require industry scientists to reprove the answers to questions that are already known, and it is wasteful to require FDA scientists to review the same evidence over and over again.

It is also critical for regulatory policy to accommodate the realities of the marketplace for medical devices. It is relatively small compared to drugs as devices are generally used to treat acute problems in hospital settings rather than to treat millions of patients over periods of years and decades. The markets for most devices used in new treatments simply will not economically support overly large clinical studies, which are limited in value anyway because the success or failure of devices is largely dependent on the ability of thousands of physicians to use approved devices in their every day practice. Experience in using devices over time provides the most reliable clinical data. Finally, while relatively small, the marketplace is global and regulatory policy must permit American manufacturers to be nimble and react to developments occurring around the world.

We hope our suggestions are helpful, but we must note that improving the regulations will not solve the most pressing problems. FDA must properly manage its operations and ensure that the

regulations are used properly. In recent years, there has been inconsistency in the review process at all levels and an alarming lack of understanding of regulatory requirements within the agency. Further, we have encountered major changes in previously agreed to requirements for our studies made by FDA with no scientific justification, and these have significantly delayed approval for several important products. Indeed, the uncertainties and delays at FDA have left our company no choice but to introduce most all of our new products outside the United States long before American patients can have access to them. To reverse this trend, leadership at FDA is critical. Staff needs to be properly trained and supervised, and the culture needs to change to recognize the importance of bringing new medical treatments to patients. With the firm commitment of leadership, there is no reason why FDA cannot approve or clear most products as quickly as any nation in the world.

Finally, we would like to comment on the importance of public and private collaboration, which is raised in the Request for Information. Innovation can start with breakthroughs in basic or applied science in government laboratories, in research programs in academic settings, and in private industry. Then it proceeds to the development of a concept for a product, design, prototyping, testing, then finally approval to market, manufacturing, training providers, and widespread use. These stages involve physicians, hospitals, academic institutions, government and, very importantly, industry. Then once a product reaches the market, it generates new ideas, most often among physicians, which lead back to industry and back into product development, testing, clinical trials, approvals, etc. It is critical that as we go forward all of the necessary stakeholders be enabled to make their contributions to this time-tested process.

Sadly, in the last several years, we have seen a growing cynicism regarding the role of industry in the development of medical technology. This is undermining our country's ability to achieve the potential benefits of the medical revolution we are experiencing. Specialty societies are distancing themselves from the very manufacturers that have provided their members with the cutting edge tools to help patients and teach them how to effectively use those tools. Regardless of structure, industry sponsored research (which comprises the majority of medical research) is denigrated. Inventors of breakthrough technologies are ostracized for receiving royalties on their inventions. Academic institutions are threatening to turn away industry-sponsored research which is absolutely essential (and often required) to develop and approve products. In our view, all of this could lead to incalculable harm to patients as new technologies are delayed, never reach the drawing board, or perhaps developed but never implemented in clinical practice. This development is not serving patients' needs.

Surely we can find a way to develop common sense rules and use transparency so that as a nation we can fully utilize all the resources available (health care providers, academia and industry) to bring new technologies to patients. We believe that government is the appropriate party to bring

all stakeholders together and to help develop consensus in this area. It would be tragic if we squander the wonderful opportunity before us.

With this said and the importance of collaboration noted, we believe it is important that FDA recognize the areas where it can be helpful and where it is likely that its contribution will be marginal. For example, the agency has recently proposed to construct a core curriculum for medical device development as part of the effort to promote innovation. As mentioned above, the American medical technology industry is the most innovative and creative in the world. Its members know how to develop new medical devices. At a time when resources are scarce, we think it would be wise for the agency to focus on areas where it has significant expertise.

Thank you very much for considering our thoughts. We wish you the very best in developing the Blueprint. This is a very important endeavor and do not hesitate to call upon us if we can be helpful in any way.

Respectfully,

Stephen L. Ferguson
Chairman of the Board

Attachment: Suggestions for Improving Performance at FDA

SUGGESTIONS FOR IMPROVING PERFORMANCE AT FDA

1. **Focusing on the mission.** The mission of the FDA is to protect and promote the public health. FDA processes and activities that do not further this mission and do not help patients should be modified or eliminated. In the course of these recommendations, we point out several areas where the processes or actions of the agency are not productive. We believe such processes and activities should be reformed or eliminated administratively or legislatively if necessary. Achieving such changes should be FDA's top priority.

2. **Recruiting and training staff.** The agency has experienced significant staff turnover in recent years, as have many private and public organizations. Like all organizations, it must develop **systems** that address recruitment and training if it is to effectively carry out its mission despite such problems. We are pleased that FDA's Center for Devices and Radiological Health (CDRH) is developing a certification program for reviewers, among other things. Training is essential if we are to minimize the inconsistencies that are bogging down agency reviews and to improve the quality of reviews. In the past, Cook has invited CDRH device reviewers to visit our facilities independent from any pending product reviews so that they can gain a better perspective on how medical device companies develop and manufacture products. Feedback from both reviewers and management was very positive, with participating reviewers gaining valuable insights into the development process. We recommend that FDA implement a formal program that assures one third of reviewers each year visit a company that makes products in the reviewers' areas.

3. **Improving the process of investigational device exemptions (IDEs).**
   - **Approval requirements.** The investigational device exemption was intended to allow distribution of a device so its safety and effectiveness could be studied. An approval of an IDE is not an approval of a product or a commitment that the approved study will result in an approval or clearance for commercial marketing by FDA.
     - It has become common for FDA to treat an application for an IDE as if it were the application for Premarket Approval (PMA) that may eventually arise from the proposed clinical study.
     - It is important that reviewers recognize the difference between the two applications. The IDE is simply a study to learn about the device. It is impossible to know the answers to all of the questions that are critical to the PMA until the study is done. Indeed, in many instances, the study will not result in a PMA. Focusing on issues related to a possible subsequent PMA causes lengthy delays in starting studies for which all relevant safety questions have been answered. Training review staff in these distinctions should be a priority.
     - While it is helpful to receive advice on items that may be of importance to FDA in a subsequent marketing application, including this advice within the formal FDA response to the IDE application frequently causes needless delays in Institutional Review Board (IRB) approval of the investigation. We recommend that FDA use a separate mechanism (e.g., a separate letter) to communicate this advice to sponsors so that clinical studies may commence upon receipt of the notification.
   - **Conditional approvals.** The practice of conditional approvals of IDE applications, although well intended, has led to confusion and delays.

- IRBs are extremely sensitive to regulatory compliance issues, and not infrequently they refuse to allow their institutions to participate in studies that have been "conditionally" approved, even though the conditions are by definition unrelated to the assurance of safety necessary to initiate the study.
- We recommend that separate letters be written, one approving the commencement of the IDE clinical study, the second addressing any ongoing deficiency questions.

- **National IRBs.** We recommend that the agency require all institutions to accept an approval by a national IRB in cases where a device sponsor has chosen to use this approach. We would also encourage the FDA and HHS to review the regulations governing the IRBs to ensure that institutions are able to accept the national IRB determinations.

4. **Stabilizing the moving goal posts.** A major problem faced by manufacturers in the premarket review process arises when changes are required by FDA in a clinical study despite previous agreement on the study protocol. It has been our experience that in many cases such changes are not based on strong scientific or public health grounds. We recommend that FDA not permit changes unless specific, scientific evidence demonstrates the clear necessity of the change to protect the public health.

5. **Utilizing international standards.** Standards are invaluable in expediting the approval and clearance processes and represent the consensus of world-wide experts. They significantly reduce or eliminate the need to repeatedly prove basic principles. While the FDA has often been involved in the development and writing of international standards, it has been slow to adopt them. In many cases, FDA issues its own guidance rather than recognizing an established international standard. International standards may also avoid the use of FDA resources in developing guidance documents. We recommend legislation that would permit anyone to petition for the recognition of one or more standards and require the FDA to recognize such standards within 180 days or state its reason(s) for not doing so.

6. **Utilizing information from premarket applications.** Until 1990, the Food, Drug, and Cosmetic Act (FDCA) did not permit the Secretary to utilize in any way information learned from premarket applications in approving other applications. In 1990, Congress amended the Act by passing Section 520(h)(4) to allow the use (but not disclosure) of such information in approving an application for another device after the publication in the Federal Register of an approval of an application for the fourth device "of a kind." The purpose of this provision was to reduce the waste of agency and industry time and resources, reduce the unnecessary sacrifice of animals, and reduce the number of human patients subjected to clinical trials as manufacturers are required to prove principles over and over again that had already been proven. Unfortunately, this provision proved too cumbersome and was never used. In 1997, Congress amended the Section to permit information from a PMA to be used six years after the approval of the particular application for several purposes, including the approval of another application. Again, the provision has proved too difficult to use.
    - It is most unfortunate that our laws have prohibited FDA from using what it has learned so that it can focus on important unanswered questions presented by a new technology. Instead, the current system requires highly skilled scientists both at FDA and in industry to expend resources dealing repeatedly with the same questions, which are really no longer meaningful questions. Further, this prohibition of using information inhibits the ability to

employ modern techniques of statistical analysis. The net result of all of this is major delay in the approval process to the detriment of patients badly in need of new therapies.

- We recommend legislation to eliminate these restrictions, which are simply barriers to entry. While trade secrets and legitimate proprietary information should be protected from disclosure and patents enforced, the FDA should be permitted to apply what it knows and expedite the process of innovation.

7. **Utilizing foreign data.** A tendency has developed within FDA to reject information developed in studies outside the U.S. that were not approved by the FDA prior to their execution. It should be made clear that valid scientific evidence is valid scientific evidence regardless of where it was originated or whether the studies were pre-approved by the agency. In regard to foreign data, it is particularly important for FDA to recognize that study protocol requirements may differ from nation to nation because of cultural or other differences. Data should not be rejected simply because the design of a protocol is different from what FDA would prefer, as long as critical patient protections are included and data gathered from the study provide robust scientific evidence for determining the safety and effectiveness of the device in question. It is clear that the international medical community recognizes published literature from around the world to assess appropriate medical care for patients. FDA should do likewise for foreign clinical studies submitted by sponsors.

8. **Taking the lead in international harmonization.** Medical devices markets are global markets, and there is a tremendous waste of resources in bringing products to market when countries have significantly different approval/clearance processes. The leadership of the U.S. is critical to developing a more harmonized global system. Specifically FDA should work to--
    - Strengthen the Global Harmonization Task Force (GHTF) and its successor organization the International Medical Device Regulators IMDRF), recognizing that industry participation is critical to success, because it is industry which bears the economic burden of complying with multiple regulatory systems as it brings new products to patients.
    - Develop a system that provides for a single approval or clearance for moderate risk (Class I and II) devices around the world.
    - Develop common standards for clinical trials that are universally accepted for approval purposes.
    - Develop an inspection process that is accepted by all regulatory authorities.
    - Develop a system that promotes adherence to international standards.

9. **Using alternatives to clinical trials.** Clinical trials should be avoided wherever there are alternative ways of providing information necessary to demonstrate a reasonable assurance of safety and effectiveness. This can be accomplished by using historical data, confirmatory studies, registries, animal studies, databases and the latest technologies in testing and computer modeling. The revolution in information technology provides us with the tools to appropriately aggregate and analyze the goldmine of data that government agencies (such as FDA, CMS, NIH, and DOD), health plans, health care providers and private industry already have available. In years to come, that data will be enriched many times over as electronic medical records become universal. This information can be used to minimize the need for clinical trials and in many instances the sacrifice of animals. It can answer many postmarket questions as well. FDA has recognized the importance of developing alternatives to clinical trials, yet on August 15, 2011, it published a draft guidance

calling for the increased use of randomized, blinded trials. The FDA needs to clarify its position and move to solutions not involving clinical trials wherever possible.

10. **Improving the humanitarian device exemption (HDE).** The HDE provides a mechanism to bring novel products for small patient populations to the marketplace. While patients have been provided access to many important products since the provision was enacted in 1990, the process has been limited by two restrictions: the profit prohibition and the 4,000 patient ceiling. In 2007, Congress removed the profit prohibition on HDEs for pediatric products and this change has led to a significant increase in applications for such exemptions, but problems remain. For instance, although pediatric devices can be sold at a profit, the sales are limited to an "Annual Distribution Number" that does not allow for patients who may need more than one device (i.e., a course of treatment) in order to be treated for their condition. We recommend the profit prohibition be eliminated for all HDEs by Congress and the concept of the "Annual Distribution Number" be eliminated. We also believe the patient ceiling should be raised to a number that represents a patient population large enough, as a practical matter, to populate a meaningful clinical trial. The current ceiling was established arbitrarily, and making this change would give it a rational basis and carry out Congressional intent to utilize the HDE where alternative approval mechanisms are impractical. Note: H.R. 3211, introduced by Rep. Bass, addresses the profit prohibition.

11. **Improving de novo classification.** De novo classification was added to the law in 1997, to fill in a gap in the approval/clearance process. There are a number of novel products that are moderate risk for which the premarket approval process is not warranted. Unfortunately, a relatively small number of products has been classified by the de novo mechanism. We recommend that the process be streamlined by eliminating the need for a formal finding of "not substantially equivalent." We also recommend that the elements that should normally be considered in the de novo process are: (a) an assessment of clinical evidence that is available and pertinent to the new device, (b) a discussion of how the risks are to be minimized, (c) a discussion of what additional clinical data, if any, must be collected to properly assess the risks, and (d) an analysis of the benefit to risk ratio of the device. Note: H.R. 3203, introduced by Rep. Bilbray, addresses the issue of requiring a formal, not substantially equivalent decision.

12. **Effective use of postmarket surveillance and studies.** Postmarket surveillance is another important aspect of the regulatory scheme for medical devices. No matter how thorough, the approval process is limited and will not detect every possible outcome from the use of a device. It is not until products are used by hundreds or thousands of physicians over a period of time for the treatment of patients with a variety of co-morbidities that we gain a broader knowledge of devices. For this reason, it is important to follow devices closely over the first few years after they are launched. For most products, which are evolutionary in nature, this is not difficult. Surveillance amounts to diligent monitoring that is best aided by a robust system of adverse event reporting. For the rare devices that are revolutionary, a more active program may be appropriate.
    - In recent years, FDA has treated most Class III products as revolutionary rather than evolutionary, when in fact most are very similar to products already on the market. These products should be well suited to simple surveillance. Requirements for unnecessary clinical studies consume immense resources from FDA, industry, and health care providers that should be used for other purposes.

- Postmarket clinical studies present a number of problems and should be required sparingly:
    - If there are several similar devices on the market with the same indications, in many instances there will not be enough available patients to populate the studies. The markets for devices are not like those for drugs in size. When several companies are seeking patients for postmarket studies, they will have great problems in finding patients and be unable to fulfill the obligations FDA has imposed.
    - Doctors are generally not interested in participating in studies regarding devices that have already been proven to be safe and effective and approved for commercial distribution. They prefer to study new, cutting edge products, where it is more likely that the study will provide new knowledge. This adds to the challenges facing the manufacturer trying to conduct postmarket studies.
    - Prolonged studies can subject patients to added interventions and risks (e.g., imaging contrast and exposure to radiation) that would not be consistent with the routine standard of care.
    - Because of the rapid development of technologies, new, improved, next generation devices often become available during the term of postmarket studies. Using an older device when better products are available or when the stipulations of the postmarket studies are not consistent with the standard of care, presents further ethical difficulties for physicians. In addition, when the longer term data are complete, they often represent the performance of a device that is no longer marketed.
- FDA should issue clear guidance that postmarket studies are appropriate only for a limited number of devices, such as new, revolutionary devices that are implants or used in new medical treatments, rather than those follow-on devices where knowledge has accumulated. Further, FDA should utilize analyses of databases, extended patient follow up, or registries whenever possible.

13. **Efficient reporting on postmarket studies.** Manufacturers of products that have been approved through the PMA process face several reporting requirements that are often redundant. If the studies conducted under the IDE are continuing, and they often are, periodic progress reports are required. If an additional study was required as a condition of approval, progress reports on that study must also be made. And, in all instances, an annual report must be filed on the device. There is significant overlap in the information contained in all of these reports, and preparing and reviewing repetitive reports is tedious and resource intensive. To reduce this redundancy and to conserve industry and agency resources and time, we believe FDA should review the information that must be reported, eliminate requirements to report information that has questionable value, and design a consolidated report that could be filed on an annual basis.

14. **Efficient regulation of modifications to medical devices.** Medical devices are constantly modified and most modifications are very minor. Such changes are tested, documented and approved internally by manufacturers under the quality system regulation. This works well. Unfortunately, FDA has issued a new guidance that we believe will dramatically increase the number of 510(k)s filed. We recommend that guidance be withdrawn. Unless there is a significant chance that a particular change will impact safety or effectiveness, the processing of such changes

is best left to the quality system. If FDA insists on taking an expansive view of the types of changes that generate the need to file a 510(k), it will waste precious resources that are best directed to much more important issues. Indeed, it would not be unusual for a company with a broad range of products to have more than 1,000 modifications in a year. Expanding its review of such changes could overwhelm CDRH and shut the system down. If the current guidance needs to be updated, we recommend the stakeholders be brought together to develop a more practical approach.

15. **Utilizing authority to down classify well known medical devices.** As experience is gained with a medical device, the questions that were legitimately asked during the approval process become fully answered. When this occurs, the agency should down classify the product to save resources to focus on the next generation of new, cutting edge technologies. Such down classification rarely happens, however. The agency does not give such action a high priority, and it is a cumbersome process which can take five to ten years. For example, a down classification petition was submitted to the Agency on August 28, 2000 and filed by FDA on September 21, 2000, the Circulatory System Devices Panel recommended on December 4, 2000 that certain PTCA catheters be reclassified from class III to class II with special controls, and it was not until a decade later that FDA issued the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters Document on September 8, 2010 (75 FR 54496, Sept. 8, 2010). To emphasize the importance of reclassification to the efficiency of the agency, we recommend legislation to authorize the agency to publish a list of products to be down classified, receive and review comments for 90 days, and then issue a rule classifying the products appropriately.

16. **Exempting products from the requirements of the 510(k) clearance process.** Experience in using a device also provides knowledge about moderate risk products that obviates the need for the filing of 510(k)s. Clear authority should be given the agency to periodically list such products, receive comments for 60 days and then issue a rule exempting them from the requirements.

17. **Inspecting efficiently.** We believe that inspections are extremely important. They make certain that manufacturers are adhering to their quality systems. Congress expected FDA to routinely inspect each manufacturer every two years. This has not happened. Fortunately, countries in Europe and elsewhere require inspections every year and this has helped to fill any void left by FDA. These inspections are usually conducted by third parties known as notified bodies. It is important to recognize current practices and take advantage of them. Congress should instruct FDA to make it a top priority to work with other nations to develop a common protocol for inspections accepted by all nations, and it should accept inspections by third parties. The requirements for inspecting every 2 years should be lengthened to every 4 years. Further, premarket inspections should not be required for companies that have been favorably inspected within one year.

18. **Utilizing third party review.** Congress authorized the agency to establish and use a third party review system for certain low-risk products. Unfortunately, third party review has not flourished. A major reason for this is that third parties are not given adequate access to information regarding predicate devices. We recommend legislation to grant such access. Further, we believe Congress should instruct the agency to give high priority to working with other nations to develop a system that provides for a single approval or clearance for moderate-risk devices (Class I and II) around

the world. Note: H.R. 3205, introduced by Rep. Paulsen, addresses in part the issue of access to information.

19. **Utilizing quarterly malfunction reporting.** Section 519(a)(1)(B) of the FDCA) requires promulgation of a regulation to provide criteria for quarterly reporting of malfunctions of moderate-risk devices in a summary format. Though this requirement was enacted by Congress in 2007, FDA has not implemented it. FDA receives thousands of malfunction reports, which overwhelm the device reporting system. Filing those reports consumes significant resources of manufacturers and attempting to review them consumes significant resources of the agency. We recommend that FDA should immediately issue regulations to implement Section 519(a) to dramatically reduce the number of individual reports submitted to the agency while maintaining full accountability from manufacturers to report every malfunction reported currently, but on a quarterly basis and in summary format that will provide FDA useful and manageable information from malfunction reporting.

20. **Revamping user reporting.** Section 519(b)(5) of the FDCA requires the Secretary to designate sentinel device user facilities to assume the responsibility for user reporting of adverse events with devices. While the agency has developed a program for user facilities known as MedSun, it has not fully implemented the program so that additional user reporting can be dispensed with. It is common knowledge that the current user reporting system is not working. At best, the agency receives a small portion of the reports that the statute requires, and then those received are not satisfactorily analyzed. Programs that do not provide value should be eliminated or replaced. This can be done by following the current statutory requirements. FDA should propose a regulation to implement the sentinel reporting system envisioned by Congress. Sentinel reporting would be based on strategically selected healthcare centers that would provide a representative profile of user reports for device deaths and serious illnesses or serious injuries. Members of MedSun would be excellent candidates for this program. Sentinel facilities would have the expertise to provide meaningful reports with useful analyses and add value to the system. They could also be given special recognition for their contribution to patient safety. Once the system is in place, the sentinel reporting could replace the general requirements for user reporting, as Congress directed, with a more robust system in which obligations are well understood and enforceable.

21. **Inspecting contract manufacturers of drugs and biologics.** Currently FDA inspects contract manufacturing organizations (CMOs) only when they have contracts to manufacture specific products. This can significantly delay the utilization of new contract facilities, as proprietary companies are reluctant to enter a contract with a CMO that has never been inspected. In view of the current drug shortages, it is essential that all manufacturing capabilities be made available as soon as possible. Since a major portion of the inspection is general in nature and does not relate to a specific product, FDA should conduct a general inspection of CMOs requesting such inspection as soon as possible, to make it clear that new, high-quality manufacturing capacity is available. This will speed the process of bringing that capacity into operation and assist the country in supplying badly needed pharmaceuticals to patients.

22. **Obtaining advice from outside.** Just as medical device manufacturers benefit from inspections and audits, so, too, could FDA. We recommend that FDA promptly retain an outside consulting firm to audit its operations and to make recommendations aimed at improving the agency's

performance and efficiency. Note: S. 1700, introduced by Sen. Klobuchar, would require a similar audit.