

**PRESENTATION OF STEPHEN L. FERGUSON
CHAIRMAN OF THE BOARD
COOK GROUP INCORPORATED**

**PUBLIC MEETING – DEPARTMENT OF HEALTH AND HUMAN SERVICES
“STIMULATING INNOVATION”**

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I am Steve Ferguson, Chairman of the Board of the Cook Group Incorporated. Cook is the largest privately held medical device company in the world. We sell over 30,000 different products. Our company has been a pioneer in interventional medicine, introducing many new technologies to the marketplace. We manufactured the first catheters used in the Seldinger technique of angiography marketed in the United States; we made the first coronary angioplasty balloon for Andreas Gruntzig; we manufactured the first coronary stents sold in the United States; our company in Australia led in the development of endografts to treat abdominal aortic aneurysms in the 1990's, and the list goes on.

In August, we submitted comments in response to the Department's request for input as to how the HHS agencies can work to facilitate the development of new medical technologies. We are honored and grateful to have the opportunity to address this task force to further highlight our views.

Before addressing specific proposals, I would like to point out some changes that have occurred in the medical technology marketplace that we should keep in mind as we discuss ways to foster innovation. First, development has moved from the clinical setting to the science. Second, medical technology markets are global markets. Internet enabled patients have information from around the world, both good and bad, and they expect to receive the latest therapies for themselves and their loved ones. Third, Americans will not accept rationing of medical technology according to ability to pay. Fourth, informed American consumers will place tremendous pressure on the political process to provide access to technology. And fifth, an expectation has arisen in the United States and elsewhere that small medical devices, which are often simply tools for the physician, should bear the cost of proving the value of new or changed medical procedures. This may work in large markets such as coronary stents, but in the smaller markets, which are more prevalent, it is problematic.

Innovation is a continuum. It begins with basic science, often in conjunction with NIH or NSF. Then it proceeds to the development of a concept for a product, design, prototypes, testing, approval to market and approval for reimbursement. There are hundreds of suggestions that could be made to deal with various aspects of innovation, but we will make only a few based on our experience as a manufacturer of cutting edge technologies. Some of our proposals are straightforward and can be accomplished relatively quickly. Others are quite complex and will take time and effort to achieve.

Many of our suggestions are related to the approval and reimbursement processes for medical devices. It is important to recognize that the burdens associated with these processes often determine which products reach patients. We should always seek to adopt the least burdensome approach. As we do so, we should measure any proposal by its benefit to patients, not by its impact upon the competitive position of manufacturers.

Utilizing Information More Efficiently

Our first group of suggestions focuses on the use of information and databases. There is a gold mine of information available to us today, and we have abilities to organize and analyze that information that were undreamed of a few years ago. If we work smartly, we can seize upon scientific breakthroughs, facilitate the development of products, and expedite the delivery of these products to patients. By properly using information, we can also save invaluable time and resources for industry, government, and academia that then can be redirected at developing the next generation of cutting edge technologies. Specifically, we believe the following steps are in order:

1. We must permit and enable FDA to utilize and share the information that it possesses.

FDA should be a source of information and should be able to guide manufacturers to essential questions that need to be answered about materials and the functions of specific products. Utilizing information efficiently will eliminate the tremendous waste of resources that occurs when known principles must be proven over and over again by each applicant. We can eliminate the need for much bench testing, and we can also reduce the sacrifice of animals. Finally, we can reduce the need for patients to be subjected to clinical trials to prove what FDA already knows. Among the types of information that could be better utilized are the following:

- Data from pivotal clinical trials, animal studies, and bench tests that support an application for the approval of a product.
- Information related to the properties of materials, biocompatibility, and clinical utility.

Using such information will also enhance our ability to employ advanced techniques for statistical analyses, including Bayesian statistics. Finally, it will facilitate the development of more sophisticated methods for computer modeling that in many instances can reduce bench testing, animal testing, and clinical trials.

2. We need to work smartly to develop data for evidence based medicine.

- Neither government nor industry has enough resources to conduct extensive clinical trials for all new therapies. Sick patients, who desperately need those therapies, do not have the time to wait for years for the completion of those studies.

- We must allow promising new technologies that have been approved by FDA to diffuse and then analyze the data that are developed.
 - Manufacturers, by working with the government to develop reasonable and practical registries, can provide some of these data. Such registries should be designed to produce needed information in the least burdensome manner.
 - Data can be significantly expanded by analyzing CMS claims data. This may require more detailed coding for the relatively small number of new technologies which emerge each year. It may also require revision of claims forms and other changes to the Medicare payment system.
 - The data can be further enriched by developing and properly analyzing electronic medical records in communities across the country.
 - We must utilize available expertise in the private sector as well as in the government to progress in this area. In Indiana, for example, we have the Regenstrief Institute which has been a pioneer in developing electronic medical records. Organizations such as Regenstrief can provide invaluable advice and provide assistance in appropriate pilot studies. Indeed, Regenstrief and the Indiana Health Information Exchange (IHIE) were recently awarded grants by AHRQ to this end and are already working with HHS on electronic medical records.
3. **Government should lead the way in exploiting the immense mountain of data available. This includes not only FDA but also NIH, CDC, NSF, DOD, and perhaps other agencies and departments. We believe these governmental entities should do a number of things.**
- Government agencies should upgrade to modern, advanced information technology systems that are compatible with each other so that they can easily exchange information and utilize each other's databases. Incompatibility of systems is a major problem, and if the government solves that problem internally, it will not only increase its own capabilities, it will set a standard that the private sector will follow.
 - Greater communication needs to occur across relevant government agencies so that all understand the broad scope of what is being developed. Currently, it appears to us that there is a huge amount of great work going on, but it goes on in silos. We need to make certain that FDA is aware of what NIH and CMS are doing and vice versa. There may be knowledge and data that one organization has that could be valuable in the approval process, or that another has that could expedite evaluation of outcomes. FDA could point out areas to NIH that are not being developed by industry but merit investment of government funds in research, etc.

- Government agencies need to maintain strong lines of communications to the private sector. This needs to be direct and specific when dealing with approval and coverage issues. It also needs to be broad and informative about the big picture to keep industry and academia informed of activities and resources that may be available.

Managing Resources Wisely

There are other steps that should be taken to clarify and streamline regulations, reduce barriers to innovation, and conserve resources that can be refocused on new technology. We recommend the following:

1. **The United States must take the lead at the highest levels to harmonize regulatory and coverage systems around the world. There is a tremendous waste of resources in bringing products to global markets, country by country, and that waste is growing exponentially. We must set an agenda and give top priority to leading the global community to accept and help achieve our goals promptly. Specifically, we must take the following steps:**
 - We must first develop a system that provides for a single approval or clearance to market low risk devices (class I and II) around the world.
 - We must develop common standards for clinical trials that are universally accepted for approval and coverage purposes.
 - We must develop an inspection process that will be accepted by all nations.
2. **We must develop clear and workable regulatory schemes for combination products and for tissue engineering both domestically and internationally. There is currently great confusion in these areas which is significantly slowing progress.**
3. **We must streamline FDA's approval process wherever possible to conserve resources. This includes the following:**
 - We should simplify and utilize the reclassification and exemption processes for medical devices that have become commodities. As we gain knowledge about products that were once novel, the risks inherent in these products are significantly reduced. This gives us the opportunity to reduce regulatory burdens for those products, and focus resources on new generations of technologies.

- We need to simplify the processes for making minor changes in IDE's. There will always be minor changes made to devices or protocols as studies go forward, and previous legislative attempts to limit regulatory requirements for making such changes have not worked well.
- We must develop a clear process to permit appropriate proof of concept studies.
- We should devise a process, with appropriate safeguards, which will allow for the utilization of data collected regarding off-label uses.
- FDA needs to minimize clinical trials wherever possible by utilizing historical data, conformity studies, and the latest technology testing and computer modeling.
- FDA should adopt more international standards, which are invaluable in expediting the approval process.
- We should revise the Humanitarian Device Exemption to provide more encouragement to manufacturers to develop products for small markets. Specifically, we should:
 - Eliminate the prohibition of profits.
 - Streamline IRB requirements.
 - Review what the appropriate size of an "orphan" market should be.

Thank you very much for the opportunity to share our thoughts with you. We commend the Department for addressing these critical issues, and we wish you the very best in this effort. This effort is important to patients around the world.