FDA RAPID RESPONSE SURVEYS
OMB No. 0910-0500
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the generic clearance, FDA Rapid Response Surveys. The purpose of the information collection is to provide a tool to obtain quickly vital information from the appropriate clinical sources so FDA may take suitable public health or regulatory action.

This program will obtain data on safety information to support quick-turnaround decision-making about potential safety problems or risk management solutions. FDA will collect this information from health professionals, hospitals, and other user facilities (for example, nursing homes, ambulatory surgical and outpatient diagnostic and treatment facilities, etc.), consumers, sponsors and manufacturers of biologics, drugs and medical products, distributors, and importers when the agency must quickly determine whether a problem with a medical product impacts the public health. While the form for data collection will be standardized (please see Attachment A – Standardized Form), the actual information to be collected will vary from survey to survey. The specific information FDA needs for risk/management or hazard analysis will depend on the medical product in question and the particular adverse event under investigation. Responses to the information collection questions are strictly voluntary and anonymous.

FDA is the regulatory agency responsible for the safety and effectiveness of medical products including biologics, drugs, foods, cosmetics, medical products, radiological products, and animal drugs. Important questions about medical products, such as those concerning user experience, durability, and rare effects may not be answered until after the product has been marketed. To protect the public health, FDA must be able to collect rapidly information pertaining to adverse events associated with medical products after they have been marketed.

Section 505 of the Federal Food, Drug and Cosmetic Act (the Act)(21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to the FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the Act (21 U.S.C. 372) authorizes investigational powers of the FDA for the enforcement of the Act.

Under section 519 of the Act (21 U.S.C. 360(i)), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions and to require user facilities (hospitals, nursing homes, ambulatory surgical facilities and outpatient diagnostic and treatment facilities) to report medical device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer.

Section 522 of the Act (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices.

Section 705(b) of the Act (21U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer.

Section 903(d)(2) (C) of the Act (21 U.S.C. 393(d)(2)(C)) authorizes the Commissioner of the FDA to implement general powers (including conducting research) to carry out effectively the mission of the FDA.

These sections of the Act enable FDA to enhance consumer protection from risks associated with medical product usage that are not foreseen or apparent during the application, premarket notification and review process.

FDA's regulations governing applications for agency approval to market a new drug (21 CFR part 314), regulations governing biological products (21 CFR part 600, et. seq.), and regulations governing medical devices (21 CFR Part 803) implement these statutory provisions.

Currently, FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting System. Using FDA forms 3500A (mandatory form) and 3500 (voluntary form) approved under OMB Control Number: 0910-0291, and Form VAERS-1 for the Vaccine Adverse Event Reporting System (VAERS), all reports are submitted to FDA.

Over the years, medical science and technology have become increasingly complex. Due to economic pressures and organizational changes within health care organizations, this science and technology is not only used by highly trained health care professionals, but has also moved into facilities where the users may not be as sophisticated. Additionally, many of these increasingly complex drugs and medical products are now found in the home. These changes have increased the need to obtain timely information from postmarket surveillance systems and to disseminate quickly information to the health care and consumer communities on public health safety issues.

Analysis of a potential health or medical problem often cannot be made based on the information contained in a few adverse event reports submitted through the MedWatch program. While section 522 of the Act gives FDA the authority to instruct manufacturers to conduct surveillance of medical devices and sections 702 and 903 to investigate and to conduct research to allow FDA to enforce the Act and to carry out the mission of the Agency. For instance, for devices, it can take up to 90 days before the surveillance plan is begun (i.e. the manufacturer has 30 days after receiving notification that FDA is requesting surveillance of a particular product to submit a surveillance plan, and FDA then has 60 days to accept the plan), and much longer until the plan has been completed. This link to the manufacturing community does not fulfill the need for rapid information when FDA must decide quickly if particular adverse event reports signal a widespread public health problem. FDA requires a timely link to the clinical community in order to obtain information for more emergent situations.

The reports of adverse events that FDA receives from the clinical community typically are not complete and hence there is considerable underreporting. When necessary, FDA contacts the individual reporter of a particular adverse event to obtain more information than what was provided in the MedWatch report. However, there is often insufficient information from the reporter to determine whether an adverse event signals a potential public health hazard. Lack of sufficient information often hampers FDA's ability to understand quickly and thoroughly and evaluate the problem; determine the factors that contributed to the adverse event; determine the scope of a possible public health problem;

and determine what steps must be recommended to the health-care community to prevent further injury.

In order to perform risk analysis and determine the appropriate action plan, FDA must have the tools to investigate fully medical product problems. Therefore, FDA implemented this information collection program, FDA Rapid Response Surveys, which provides the necessary timely link to the clinical community**.**

No more than 30 rapid response survey questionnaires will be sent to the appropriate medical professionals, health care institutions, consumers, sponsors, manufacturers and/or importers of medical products each year. The data collected will provide FDA with information to allow a more complete analysis of the problem; determine the existence and extent of a public health problem; and then, if necessary, to disseminate the information to the health care community. All of these processes must be accomplished in a timeframe that limits, to the extent possible, further incidents causing injury to the public.

A standard survey form will be used, with the addition of questions that specifically address the medical product problem under investigation. Prior to sending out each survey, FDA will send a memorandum with the survey attached to OMB for its sign-off. FDA requests that OMB sign-off be obtained within 3 to 10 days.

2. How, by Whom and For What Purpose the Information is to be Used?

FDA monitors the reports of adverse events associated with the use of medical products that enter the MedWatch mandatory and voluntary reporting programs. Reports are triaged based on perceived risk to the patient. Some reports signal an immediate hazard, but more commonly it is the experienced FDA clinical analysts that detect product problems, particularly those related to product use, through careful investigation of reported incidents and searching for additional sources of information.

The degree of perceived risk to the public is the most important consideration for any FDA public health action (product recall, Safety Alert, Public Health Notification, Ad Hoc Committee, workshop, publication, etc.) It is imperative that these risk determinations are completed as quickly as possible to avoid further deaths or injuries from occurring. Currently, FDA analysts makes these determinations based on information contained in adverse event reports; obtained from contacting the individuals who made the reports; gathered from expertise of scientists within, and sometimes outside, the agency; and from any other data sources available.

When these data sources fail to provide enough information to perform a risk/hazard analysis, FDA proposes to use the FDA Rapid Response Surveys to answer these important questions. The variety of problems seen with medical products dictates that each survey effort will be unique in that each will involve a different type of product used by different health care professionals. For example: an adverse event report may be received describing an anaphalatic-type reaction during the use of a certain catheter. Evaluation of this problem includes questions such as: was this reaction related to the patient's illness or the stress of the procedure; and is therefore not medical product related or, is there a biomaterial in this medical product that could cause this reaction? Because the health care community often does not recognize that a product may have contributed to an adverse event and because there is significant underreporting, it is critically important to know whether other health care professionals may have seen this problem. These other professionals may have not reported a similar event because they did not recognize that the reaction might have been related to the product. If FDA has the ability to survey quickly the appropriate user population (in the example cited, this would be the IV Nurses Association), FDA could

immediately determine if the report was an isolated incident or had occurred more often and was a signal of a potentially serious problem with the product.

The targeted population to respond to the particular survey questions, and the specific survey questions, will change depending on the particular product in question.

The data will be collected and analyzed by the Agency's postmarketing surveillance offices conducting the Rapid Response Survey. Public health analysts and epidemiologists, and when necessary, statisticians and other Agency scientists, will analyze the data to determine whether a public health risk exists, and how it must be addressed.

As directed by OMB's terms of clearance of approval of this information collection a summary follows at the end of this justification provided by the Centers on rapid response surveys they have conducted over the past 18 months.

3. To What Extent the Collection of Information involves the use of Automated, Electronic, Mechanical, or Other Technological Collection Techniques

The methodology for contacting the reporting sample will vary depending on the product and the health professionals and others targeted as respondents. Some of the data collections will involve mailings from FDA, some will be accomplished with the help of professional associations (either direct mailouts from the associations to its members, or the associations may provide contact lists to FDA), and some will be conducted electronically.

Whenever possible, and on a small scale, and to avoid the burden of responding by mail, electronic collections will be conducted. For example, as directed by the Food and Drug Modernization Act of 1997, FDA is developing a "sentinel" system to represent the various types of user facilities in the United States. In order to comply with the Government Paperwork Elimination Act of 1998, these facilities will report to FDA via the Internet, and FDA will have the ability to contact the sites via e-mail. This system is currently in place, will eventually represent a group of hospitals, nursing homes, home health care agencies, and other medical product user facilities. The risk managers at different groups (hospitals, nursing homes, etc.) of these sentinel sites would function as the sample when the product in question is used at their type of facility.

4. Describe Efforts to Identify Duplication

FDA scientists routinely utilize literature searches and other secondary data sources to aid in answering some questions about the use of medical products. However, many of the product issues relate to emerging technologies and sciences where little has been written about these problems. FDA's surveillance system is a large national system that is designed to pick up not only common problems, which may appear in the literature, but more importantly, to pick up signals for seemingly rare events that may have far reaching public health implications. These rare events usually have not been identified previously, or when they do appear in a journal, they are reported as "case studies" which do not provide FDA with the broader scope needed to define the public health impact.

Manufacturers are contacted routinely to learn of their experience in investigating and evaluating particular issues. Additionally, FDA scientists contact other public and private health organizations and associations, such as the Center for Disease Control, Product Quality Research Institute, American Association of Pharmaceutical Scientists, Generic Pharmaceutical Industry Association, National Association of Pharmaceutical Manufacturers, Nonprescription Drug Manufacturers Association, National Pharmaceutical Alliance, Parenteral Drug Association, Pharmaceutical Research and Manufacturers of America,

American College of Radiology, Senior Citizen Groups, or ECRI (formerly the Emergency Care Research Institute), to determine if the databases maintained at those organizations contain any useable information. In addition, FDA will contact other experts in science, medicine and public health as well as consumers, product sponsors and manufacturers, importers, and retailers.

While these outreach efforts can be useful, they may not be complete enough to aid FDA in determining rapidly the exact nature and public health impact of a problem. Therefore, FDA needs the additional tool of the information collection proposed in the FDA Rapid Response Surveys requested in this document.

5. Small Business

It is possible, but unlikely; that respondents contacted will be small businesses. Most medical product adverse events that will be under investigation are rare events, and larger institutions are more likely to have experience with these medical products. In the event that smaller entities are included in a survey, their participation will be voluntary and the burden estimated as no more than .5 hours per respondent.

6. Describe consequences to Federal program or policy if the collection is not conducted

The FDA postmarket surveillance program will be less effective in providing timely, necessary information to the health care community on avoiding serious injuries and deaths with medical products for those products whose problem mechanisms are not well understood and for which FDA has no tool to obtain needed information.

To demonstrate the importance of establishing a Rapid Response Survey information collection program**,** two sample surveys are provided (Attachment B). This sample demonstrates when an immediate means of information collection would have resulted in more effective, timely feedback to the public.

7. Special Circumstances

Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of the questionnaire.

Given the need for FDA to obtain information about possible risks to the public health in a rapid timeframe, 30 days will be the outside limit of the requested length of time to respond. If there is the possibility of a public health emergency, respondents may be asked to respond within 15 days. For any necessary shorter turnaround timeframes, electronic contact will be made to encourage faster responses.

8. Describe efforts to consult with person outside the agency to obtain their views on the availability of data, etc.

In accordance with 5 CFR 1320.8(d), on January 7, 2004, (69 FR 923), a 60-day notice for public comment (Attachment C) was published in the Federal Register. FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

Respondents will receive no gift or payment for their participation in the questionnaires.

10. Assurance of Confidentiality (Anonymity) Provided to Respondents

The identity of the respondent providing information to the FDA Rapid Response Surveys will be anonymous.

Written or electronic questionnaire forms sent from FDA will not ask for identifying information and they will not be coded in any way that will identify the respondent. Therefore, FDA will not know the identity of the respondent to any returned form. E-mail surveys will give clear directions that the responses are not to be returned via e-mail. To avoid creating a link between the respondents' responses and the respondents, the surveys must be copied from the e-mail, and faxed or mailed to FDA. Identifiers on faxed data will be removed and return envelopes will be destroyed before the information is given to the analysis team.

Whenever possible, we will work through a third party (i.e. health care association) so that the third party may contact a particular respondent for follow-up when necessary, while still keeping the identification of the respondent unknown to FDA.

Lists of all responder samples used for each inquiry will only be held long enough to determine the response rate and to re-contact each respondent if we have not achieved a response rate that permits FDA scientists to judge whether a public health hazard exists. Lists will be destroyed following the data collection and any necessary follow-up so no possible link may be made between the obtained information and the respondent. For more detail concerning follow-up of non-responders, please see Part B, Section 3.

11. Justification for Sensitive Questions

None of the questions will be sensitive in nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

This is based on the maximum number of surveys (highly likely that this maximum will not be reached--most respondents will probably never be contacted more than 5 times per year due to the variable nature of the medical product issues and the need to access different respondent groups).

Estimated Annual Reporting Burden

Number of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
200	30 (maximum)	6,000	.5	3,000

Annualized Hourly Costs

Risk managers working in hospitals will complete the majority of the surveys. The average salary of this professional group is $34.00 per hour. The estimated annualized annual cost for 3,000 hours of reporting time is $102,000.00.

The number of respondents was determined by the maximum sample size of 200 facilities (or individuals) per questionnaire. This number will vary depending on the medical product under evaluation. Data from more than 200 sources could not be evaluated in a rapid timeframe.

The annual frequency of responses is determined by the maximum number of questionnaires that will be sent to any individual respondent. As noted earlier, some

respondents may be contacted only once per year, while another respondent may be contacted several times depending on the medical product under evaluation.

The total annual responses is estimated to be 200 facilities/sample x 30 questionnaires = 6,000 (unlikely this maximum will be reached). At a maximum, it will take .5 hours for a respondent to gather the requested information and fill in the answers. The total annual burden, therefore, is estimated to be 3,000 hours (6,000 total annual responses x .5 hours/response = 3,000 hours.)

13. Estimate of Other Total Annual Cost Burden to Respondents

There will be no costs incurred by respondents.

14. Annual Cost to the Federal Government

It is anticipated that half of the total number of surveys per year will be issued via e-mail, and the remaining half will be conducted via mailings. Using the maximum number of 30 surveys per year, costs listed below are for 15 surveys conducted by e-mail and 15 by mail.

The cost of administrative help to develop the respondent lists and obtain e-mail addresses is $2,400.00. This represents .06 FTE for 120 hours at a cost of $20.00 per hour (includes administrative costs).

For the 15 surveys conducted by mailings, the cost to the government for administrative help to create respondent lists, photocopy, and stuff envelopes is $1,620.00. This represents .03 FTE for 81 hours at a cost of $20.00 per hour (includes administrative costs).

The cost of postage will be $2,220.00 (to send out 3000 envelopes and for the return postage); the cost of envelopes will be $150.00 (3000 mailed from FDA, and FDA will provide return envelope); and the cost of paper will be $81.00. **Total Cost**: **$6,471.00**

15. Explanation for Program Changes or Adjustments

There are no changes or adjustments.

16. Plans of Tabulation and Publication and Project Time Schedule

Rapid Response Surveys can provide information on potential risk to patients, but they do not yield quantitative data about safety that can be generalized. Policy makers can use Rapid Response Survey findings to test and refine their ideas, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

With this in mind, FDA will disseminate Rapid Response Survey findings only when appropriate, strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public", and will include specific discussion of the limitations of survey results with regard to
being non-quantitative and not generalizeable. Information quality encompasses (1) utility, the usefulness of the information to its intended users, including the public; (2) objectivity, whether
information is being presented in an accurate, clear, complete, and unbiased manner; and (3) integrity, the information is protected from unauthorized access or revision. FDA uses a number of mechanisms to ensure the quality of the information we disseminate. FDA reviews the

quality of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance, and dissemination.

17. Reason Display of OMB Expiration Date is Inappropriate

The OMB number and expiration date will be listed on the standard survey form.

18. Exemption to Certification for Paperwork Reduction Act Submissions

No exemptions requested.

B. Collection of Information Employing Statistical Methods

1. Potential Respondent Universe and Sample Selection Method

FDA will identify the respondent universe for each Rapid Response Survey. The appropriate respondent (i.e. typically risk managers, but occasionally nurses or physicians) for each survey will be determined by the medical product issue and the surveillance questions to be answered. However, to provide some general understanding of the size of potential universe samples, please see the example below:

Number of risk managers belonging to the American Society for Healthcare Risk Management is approximately 3,600.

Number of hospitals is approximately 6,000.

FDA has available lists of professional organizations and medical institutions. These lists are kept up to date and used when the agency is sending out Safety Alerts and Public Health Advisories. These lists are one source of identifying potential respondents for these FDA Rapid Response Surveys. FDA also has excellent working relationships with professional organizations that have offered to assist us in identifying respondents for these data collection efforts. The American Society for Health and Risk Management is such an example.

Additionally, as noted earlier, directed by the Food and Drug Administration Modernization Act of 1997, and in compliance with the Government Paperwork Elimination Act of 1998, FDA has developed a "sentinel" system to represent the various types of user facilities in the United States. Risk managers at different groups (hospitals, nursing homes, etc.) of these sentinel sites would function as the sample when appropriate, and would be contacted electronically.

FDA proposes to draw a purposeful sample of respondents for each survey. Since the survey data will not be used for estimates of incidence, there is no need for a probability sample, and in fact, the selection of a probability sample would significantly delay the data collection effort, and increase the likelihood of more injuries occurring before FDA could take action. Finally, because the proposed data collection is qualitative, not quantitative, and because FDA resources for processing incoming data are limited, FDA proposes to try to keep each data collection effort to not more than 200 respondents.

A 70% response rate is expected. The impact of a lower response rate to any given questionnaire will be considered before FDA takes action to improve the response rate. FDA may determine that action is required based solely on only information from a few sources. The individuals analyzing the responses are clinical experts in the medical product under investigation. Therefore, if the response rate to a particular survey is low, but a

problem pattern is noted in the obtained responses, FDA will act immediately without additional non-response follow-up. The goal of the information collection program --i.e., to obtain data to perform a risk analysis and to provide the public with important information about possible hazards with medical products as soon as FDA becomes aware that such hazards exist -- could be met without additional follow-up.

In other situations, a high non-response rate might prohibit FDA from determining whether a public health hazard exists. In these situations, FDA will do follow-up by mail (please see #3, below for details).

2. Information Collection Procedures

Once FDA identifies the need for additional surveillance data to address a potential public health hazard, the appropriate respondents will be identified either through FDA's lists or through the appropriate professional organizations. FDA's sentinel group will also be used as respondents.

As described in #1, above, there is a need to require specialized sampling procedures. The reasons for purposeful sampling include:

- the need to obtain targeted information from facilities or professionals which have the most experience in the use of certain medical products;
- the data will not be used for estimates of incidents, so a probability sample is not required, and may even be deleterious to the timeliness of the process;
- the proposed data collection is qualitative, not quantitative; and,
- the limited resources available at FDA.

FDA, therefore, proposes to draw a purposeful sample of respondents for each survey and the number of respondents will be selected based on the information needed, the type and availability of the appropriate respondent, and the potential seriousness of the issue. The number of respondents usually will not exceed 200 per survey.

FDA will contact the facilities and health care professionals electronically, whenever possible, or by mail.

Respondents will be asked to send in responses 30 days from the date of initiation of the survey. In the rare occasion when FDA requires immediate information, respondents will be asked to respond in a shorter time frame.

When the surveys are returned, all facility identifiers will be removed (i.e. return envelopes destroyed; and respondents contacted electronically will be told not to respond electronically, but to send faxed responses - facility information will then be removed from faxed responses). The surveys will be processed and the data sent to the analysis team.

Results will be characterized primarily using descriptive statistics since FDA generally lacks sufficient denominator information to do more sophisticated analysis. Again, the information collection is to obtain qualitative data not quantitative data. The data collected will be used to determine the risk to patient safety and to aid in developing appropriate FDA actions.

Degree of accuracy needed. The purpose of the emergency surveys is to collect information in an expeditious manner, which will help FDA to better understand a particular medical product problem to determine whether a public health issue is emerging. Whenever FDA has contacted health professionals who reported an adverse medical product event for more information, the individuals have been diligent in responding to FDA's questions and accuracy has not been a problem. Therefore, we fully anticipate that the health professionals contacted for each survey will respond with information that is as accurate as possible at the time of receiving the survey questions.

If the need arises to perform long-term evaluations of a particular problem, FDA will come forward with research agendas to obtain more analytical information and will submit the proper request for a collection of information request to OMB as needed.

3. Methods to Maximize Response Rates

Every effort will be made to maximize response rates. In discussions with the American Society for Healthcare Risk Management, it was clear that respondents must feel confident there is no identifying information on the response forms, including any link to match the form with the name of an institution or individual on the sample list. Thus, to encourage maximum response rates, FDA will destroy any identifiers on response forms before giving the data to the analysis team.

In situations where a high non-response rate might prohibit FDA from determining whether a public health hazard exists, FDA will do follow-up by mail. Three days after the requested date of response, FDA will issue a second letter to all respondents and will delineate further the need for those who have not responded to do so. All respondents must be contacted with this second letter since FDA will not know who has, and has not, already responded.

If the second letter does not obtain increased participation, FDA will contact the professional association(s) representing the respondents and request that the association aids in the collection of the information. Respondents may be more comfortable sending the responses to their association rather than to a regulatory agency.

4. Test of Procedures

FDA has utilized this method of data collection for many years, on a much smaller scale. The scientists at FDA routinely contact the reporting facility to obtain additional information. While this answers specific questions related to a specific report, it is limited in scope. Often we need information from additional facilities. This information will be obtained through use of the FDA Rapid Response Surveys.

The Consumer Product Safety Commission utilizes a survey method almost identical to the one described in this proposal with highly successful results.

Further, we have presented the methodology described in this proposal to the association cited earlier (representative for risk managers) to obtain its input. The association agreed that the voluntary, anonymous approach described is the best means to obtain critical information in a timely manner.

5. Statistical Consultation and Independent Review

Depending on the issues under evaluation, to analyze the data the analysis teams will be set up in the Centers that are proposing to use this Rapid Response Survey mechanism.

Rapid Response Surveys for CDRH

Overall comment: These surveys have been immensely useful to FDA in helping it determine whether or not possible signals it may be picking up from the adverse event data base are, in fact, isolated instances or are signals of a wide-spread public health issue. Additionally, they have provided very useful information that other clinicians may find helpful.

One of the important things we have learned from conducting these surveys is that regardless of the rate of response, all information collected was highly useful to FDA. We sincerely hope to have these Rapid Response Surveys renewed – they are a valuable tool to FDA.

1. Drug-Eluting Stents:

Actual survey response rates: This was a prospective data collection, so determining actual response rate is difficult. We received 44 reports about cases of thrombosis or hypersensitivity reactions after implantation of drug-eluting stents from 18 of the 28 sites which agreed to participate in this 6-month study. The other 10 sites stated they did not have this type of adverse event during the study period. It is unknown if the 18 sites which did respond sent us all of the events – but it appears that we had 100% of participation on some level – 18 sites sending in reports and 10 sites 'on the lookout' for these problems. Additionally, we received baseline reports from 27 of the 28 sites, which is an excellent response rate.

Representativeness of the sample: Drug-eluting stents were fairly new to the market when we began this study. FDA had received reports of thrombosis and hypersensitivity reactions in the MAUDE database and needed to further explore if these problems were tied to device problems or use problems. While this was a small sample, it did include many of the large hospitals in the country which were using this new technology. The physicians implant the stents were those with relatively little experience to those with much experience – part of clinical trial.

Actual use of the survey data: This data was very useful to the Action Team. These 44 reports were consistent with literature in the medical journals and with what the manufacturers were telling FDA. The issue appears to be tied to the patient's not continuing Plavix therapy as prescribed by the physicians. This 'real-life' experience from hospitals performing numerous drug-eluting stents added an important evaluation view for the team.

2. Pulmonary Catheter:

Actual survey response rates: 2,302 hospitals from the American Hospital Association sample frame were selected to be contacted because their demographics indicated they had a Catherization laboratory (Electro physiology (EP) monitoring labs are part of Cath labs). From these contacts it was learned that 130 of these hospitals did not have Cath labs. Therefore, 2,162 Cath labs were called. Ninety-nine refused to talk to the caller. Of the remaining hospitals, it was found that 1918 did not have an EP lab as part of the cath lab, or they did not have any experience with the device in question.

The final sample was therefore 145 sites which did have a Cath lab and which did use the EP pulmonary catheter in question. Of these, 58 EP lab directors responded to the survey. For this survey there was a 40% response rate.

Representativeness of the sample: During the work conducted to find a sample frame of hospitals with EP labs which also used the catheter in question, it was discovered that this

particular catheter is not that widely used. Therefore, the sample used is highly representative of the use of the catheter.

Actual use of the survey data: The data is currently being analyzed.