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Supporting Statement

FDA Survey of Physicians' Perceptions of the Impact of Early Risk Communication about Medical Products

A. JUSTIFICATON

A1. Need and Legal Basis

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the Act, 21 U.S.C. 393(d)(2)).

Also under the above section of the Act, FDA is engaged in a variety of communication activities to inform health care providers about new risks of regulated medical products, including prescription drugs, biologics, and medical devices (for example, pacemakers, implantable cardiac defibrillators, coronary stents, orthopedic implants, infusion pumps). More recently, FDA's communication activities have also included the general public. Communications activities include, but are not limited to, communications through the press (press releases, public health advisories) and in medical journals, letters to health care providers sent out in cooperation with product manufacturers, and notifications and information sheets about recalls, withdrawals, and new product safety information on FDA's Internet site.

Extensive publicity regarding serious side effects from certain commonly used prescription drugs, as well as certain implantable medical devices, has spurred public pressure to make risk information available sooner. In opposition to such public pressures, however, at least some prescribers and medical societies have suggested that early disclosure of potential side effects (emerging risks) may have unintended negative effects on patient care. For FDA to plan informed programmatic communication activities we need better empirical data on the impact on providers and patient care of disseminating emerging risk information.

Research is limited not only concerning the impact of communication from FDA to the public, but also concerning specific barriers to the likelihood of physicians reporting patient adverse events to FDA or to product manufacturers. Such reporting provides the basis for identification of emerging risks associated with regulated products. Therefore, optimizing such reporting is critical to the public health. Yet we have no data evaluating FDA's efforts to improve reporting.

Given differing perspectives on the value and timing of providing risk information to medical experts and the public at large, FDA believes it is critical to assess how well it is communicating with physicians – the health care provider group with primary responsibility for deciding whether to use medical products to address patient problems. This information is critical both to plan programmatic communication activities and to improve the effectiveness of

our reporting systems. Therefore, FDA plans to conduct a survey of a nationally representative group of physicians about these issues.

Key information to be collected includes the following topics:

- The impact on physicians, their patients, and their practices of the disclosure of still uncertain, emerging risks associated with medical products.
- How physicians currently receive and ideally would like to receive new risk and benefit information about medical products (for example, at what level of certainty regarding causality and through what communication channels).
- How physicians perceive the credibility of FDA and other potential sources of risk and benefit information, including product sponsors, medical societies, and the media.
- What FDA might do to increase the likelihood that respondents will report to FDA or to manufacturers serious patient reactions that might signal side effects of using medical products

A2. Information Users

The physician survey is a new information collection. It will be conducted through telephone interviews with a national probability sample of office-based physicians who engage in patient care at least half-time. The sample, consisting of both primary care practitioners and specialists, will be randomly selected from the American Medical Association's Physician Masterfile. FDA proposes to stratify the sample such that one-half will consist of primary care practitioners and the other half will consist of specialists who use medical products (prescription drugs and devices) that have been the subject of recent emerging risk communications.

The specific dependent variables for this study are outlined below. Attachment A contains a copy of the physician questionnaire.

Question #s	Variables Measured
D1-D7	Screener/demographics, including practice setting, specialty, % of time devoted to patient care, average number of prescriptions written/week, annual average of care given to patients with implanted devices
1-2	When is ideal time to receive emerging risk information
3-21, 26	Trust in emerging risk information received from various sources, how to title such information, print news source
22-25	Extent to which other information should be included in notices about emerging medical product risks
27-37	Impact of emerging risk information on physicians, patients, and practice
38-41	Current means and perceived helpfulness of receiving emerging risk information via electronic means or Internet
42-43	Awareness of MedWatch (FDA's adverse event reporting program)

44-50	Awareness, perceptions, and use of FDA's web site for emerging risk information
51-61	Awareness, perceptions, and use of 2 forms of FDA communication about emerging risk information (health care provider information sheets about drugs and medical device public health notifications)
62-73	Experiences reporting adverse events, perceived barriers to reporting

The survey data will be collected by Synovate, an independent contractor. Synovate has extensive experience conducting physician surveys.

The survey results will be used to inform a number of FDA communication activities. A recent Institute of Medicine report ("The Future of Drug Safety") critiqued the variety of communication tools and activities FDA uses to communicate medical product safety information. Partly as a result of this report, the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health are in the process of drafting risk communication strategic plans and need the information from this survey to most effectively determine how to plan the allocation of limited resources. In addition, FDA is assessing the effectiveness of its press and internet presence and tools for various audiences to determine how best to communicate emerging medical product risk information. Without empirical data on the awareness of use by physicians – a significant target of FDA's communications – such planning will not be ideally informed.

A3. Improved Information Technology

The burden for the telephone survey will be minimized by entering information collected through the CATI system (Computer Assisted Telephone Interviewing) directly into a computer. The CATI system also ensures that skip patterns are automatically followed, and response entry is much less subject to error.

A4. Duplication of Similar Information

A review of the literature reveals that there are no surveys of nationally representative office-based physicians that collect information about their perceptions concerning new and emerging risks associated with medical products and their perceived impact. While much of the literature focuses on the importance of risk communication and the characterization of major challenges in communicating risk information, the focus is based on the perspective of the physician-patient relationship (Bogardus, Holmboe and Jekel, 1999). Nor are there studies that assess how physicians currently receive and would prefer to receive emerging risk and benefit information associated with medical products. FDA plans to use the data collected from this survey to assess how physicians perceive the credibility of FDA, product sponsors, medical societies and the media regarding their dissemination of risk and benefit information. No data currently exist

concerning what actions FDA might take to encourage reporting of serious patient reactions associated with medical product use.

A5. Impact on Small Business

This data collection has no impact on small businesses.

A6. Consequences of Not Conducting the Collection

This study is a one-time data collection. Without this data collection, FDA will not be able to determine: how physicians receive emerging risk information about regulated medical products; physicians' perceptions about the credibility of sources of information and when such information is most helpful to them; the extent to which physicians are aware of FDA's efforts to communicate emerging medical product risk information; the barriers to physicians reporting adverse events associated with medical product use; and the effectiveness of FDA's efforts to improve such reporting. This information is critical to effective FDA planning of future risk communication activities.

A7. Special Circumstances

This collection fully complies with 5 CFR 1320.5. There are no special circumstances associated with this information collection.

A8. Public Comments and Consultation Outside FDA

In accordance with 5 CFR 1320.8(d), on July 31, 2006 (71 FR 23200), FDA published a 60-day notice requesting public comment on the information collection provisions (Attachment B). Comments were received from five public entities consisting of 3 for-profit companies, 1 professional association, and 1 industry trade association. All commenters supported FDA's belief in the value of conducting the survey. One commenter clearly was not aware that they could request the draft questionnaire, so specified that it could not provide detailed comments. However, that commenter made a number of general points which are discussed below.

- FDA agrees with the commenter that questions should be clear and not leading or ambiguous and that pre-testing should be conducted.
- FDA agrees that terminology used in the questionnaire should be defined clearly
- FDA agrees that the sample size will be sufficient to provide statistically relevant information for the two stratified segments of physicians (primary care versus specialty) and the combination of these two segments, given appropriate weighting to assure that the segments are combined proportionate to their representation in the physician population.
- The commenter asked whether FDA had considered including other health care providers "who prescribe drugs." First, the survey does not focus exclusively on drugs. It is designed

to examine drugs, including biologics, and medical devices. Second, and more important, FDA agrees that other health care providers get and use information about medical product-related emerging risks. However, physicians are the largest group targeted for such information, probably because they are still the major prescribers and users of FDA-regulated pharmaceuticals and devices. That is why we have focused on them for the purposes of this survey. While we would like to get information from other health care providers, we needed to assess the value of doing this against the risks of diluting the both the possibility of getting the representative experience we are tapping as well as the precision of the estimates we would get if we included, for example, pharmacists, nurses, nurse practitioners, and physician assistants. As it stands, we are already carefully selecting included physician specialties with the goal of ensuring that the samples have sufficient experience with both pharmaceuticals and devices to answer our questions in an informed fashion and provide sufficiently precise estimates of population parameters. The sampling frame we are using allows us to have this kind of control for physicians. In contrast, we are unaware of sampling frames for other health care providers that give the degree of specialization that would enable us to ensure that other providers who might be sampled will have the broad experience base we are seeking.

- The commenter observed that some of the general information source categories mentioned in the request for comments could have multiple outlets – the specific example given was product sponsors. The commenter suggested that any lack of specificity in asking about information from these sources "will limit the clarity and utility of the data collected." A second commenter suggested that FDA ask about the role of Medical Science Liaisons, an information channel that product sponsors often use. We agree that some sources, especially the one mentioned, use different outlets (channels, media) to disseminate information. However, we do not agree that a source "focus," given that we are looking at credibility issues, will result in a major limitation of the data. While the channel of communication used may affect the likelihood of a member of a target audience getting specific information, it should not significantly affect the credibility of information coming from a particular source. Credibility is most clearly recognized as a source characteristic, not a channel characteristic. Further, from a practical perspective, going to the level of channel within particular sources will make the questionnaire excessively lengthy and boring and will raise the likelihood of early terminations, as well as forcing us to delete other important questions, for very little practical gain. We ask about channels in the context of questions that have more practical utility for FDA's use (see questions 34-57).
- Finally, the commenter questioned the value of including questions about increasing physician reporting of serious patient reactions, asserting that this topic appears to be unrelated to the overall questionnaire topic. FDA agrees that the questions about how physicians communicate patient reactions (also known as adverse events) to either FDA or the product manufacturer are not the major focus of the study. In fact, only a small portion of the questionnaire addresses this topic (questions 58-69). However, such reports are critical to FDA's surveillance activities and our ability to identify early signals of potential problems. Further, given that risk communication is accepted as a two-way, interactive, process (IOM, 1989), and that estimates of the number of spontaneous reports FDA receives represents only a very small portion of actual events, we believe that ignoring this potential problem spot is inappropriate. Further, the study's funding source, the Office of the Assistant Secretary for

Planning and Evaluation, expressed a specific interest in getting more information about this issue. FDA agrees with the commenter that, ideally, we would want to focus on methods to improve quality and completeness of the reports, rather than just improving quantity. However, we believe that we need to identify the overall barriers to reporting first, before we start trying to improve report quality. We also believe that some of what we learn will give us initial insights into how to investigate further methods to improve report quality.

Two commenters mentioned that communications need to address the benefits as well as the risks of FDA-regulated products. FDA is actually concerned that a question or questions that directly address the inclusion of benefits would not provide easily interpretable results. Physicians could respond, perhaps defensively, by asserting that they don't need to be told the benefits – they already know them. This would be inconsistent with the research that clearly suggests that effective risk communication generally does not focus only on risks. FDA also believes that this issue is more one of policy and implementation and outside the scope of this survey's purpose. The degree to which specific product benefits, or risks associated with ceasing use of a particular product, should be included as part of a risk communication message will depend on the specifics of a particular case. The current questionnaire focuses on specifics relating to **when** messages should be communicated and **what** sources of those messages would be most credible. Despite this belief, FDA agrees that it would be useful to address this comment more indirectly and has added a set of questions (Questions 22-25) asking what additional information physicians would find useful to have included in notices about newly emerging product risks, including product benefits explained so that patients can understand them, and including data about the risks of not treatment patients for the product's indicated use.

FDA presented the draft questionnaire to a group of experts attending a expert "Think Tank" Workshop on "Effective Risk Communication," sponsored by the Agency for Healthcare Research and Quality, and FDA in September 2006. Approximately 40 experts discussed and provided feedback on the questions in 4 informal break-out sessions. Their comments were recorded by facilitators and considered in revising the questionnaire. A sampling of individuals providing comments includes the following.

Mary Brown, Ph.D.
University of Arizona
Tucson, AZ

Louis Morris, Ph.D.
Louis A. Morris & Associates
Dix Hills, NY

Marcus Reidenberg, MD
Weill Medical College
Cornell University
New York, NY

Jon Richter
Pfizer
New York, NY

Edwin Slaughter
Merck & Co
North Wales, PA

Paul Slovic, Ph.D.
Decision Research
University of Oregon
Eugene, OR

A9. Payments or Gifts to Respondents

Research on the effects of incentives on physician response rates has demonstrated that physician surveys without incentives can expect response rates up to 50% lower than surveys with incentives (e.g., Berry & Kanouse, 1987; Donaldson et al., 1999; Gunn & Rhodes, 1981; Kasprzyk et al., 2001; Kellerman & Herold, 2001; Tambor et al., 1993). The nature of their business - constantly seeing patients - requires physicians to make a special effort to block out some time for survey participation, and therefore requires more than a usual amount of coordination to arrange. As noted in an OMB-sponsored symposium on Providing Incentives to Survey Respondents, it has become standard practice to offer an incentive when interviewing physicians (Council of Professional Associations on Federal Statistics, 1993; Moore, 1992), and is an integral part of the survey process to achieve respectable response rates. Physicians have become accustomed to being compensated with an honorarium for their time spent completing surveys.

FDA conducted a field experiment on physician incentives in 2001 where it varied incentives to physicians for a similarly lengthy telephone survey. Physicians were randomly assigned to receive a $50, $75, or $100 incentive for their participation. The results indicated that the larger the incentive payment, the higher the response rate for the survey. A monetary incentive of $75 has been suggested by the Contractor as an honorarium to be offered to participating physicians.

A10. Confidentiality

All data will be collected with an assurance that the respondents' answers will remain confidential. A statement that responses will be kept confidential will be printed on the prenotification letter sent to potential participants prior to being called by the contractor.

Identifying information will not be included on the data files delivered to FDA. The contractor, Synovate, has standard procedures for assuring the confidentiality of survey respondents. All of the contractor's employees sign a statement agreeing to maintain confidentiality of data. Access

to the data files can only be gained through the use of a password which will be specific to this study. Names and mailing addresses for the sample will be retained only until validation and editing are complete; they will be stripped from the database before the data are sent to FDA. All computer data will be maintained in a manner which is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

Confidentiality of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b), and by part 20 of the agency's regulations (21 CFR part 20).

A11. Sensitive Questions

This survey does not include any questions of a sensitive nature.

A12. Hour Burden Estimate

FDA estimates the total estimated burden imposed by this collection is 258.1 hours annually, for a one-time collection. FDA estimates that 1000 physicians will need to be screened, taking approximately 1.5 minutes each, to obtain a respondent sample of 900. FDA estimates that the interview will take approximately 15 minutes to administer and that the variation in burden across respondents will be small. In order to evaluate the clarity and consistency of the survey questionnaire and interview protocol, up to 27 pretests (in 3 sets of 9 each) will be conducted. FDA estimates that each pretest will take approximately 20 minutes.

Estimated Annual Reporting Burden					
Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretests	27	1	27	.3	8.1
Screener	1000	1	1000	.025	25.0
Survey	900	1	900	.25	225.0
	Total				258.1

There are no capital costs or operating and maintenance costs associated with this collection.

A13. Costs to Respondents

There are no costs to respondents associated with this data collection effort outside of the burden reflected in A12.

A14. Annual Cost to the Federal Government

The total estimated cost of this research is $210,000. This includes fees paid to the contractor to program the study, obtain the sample, collect the data, and create a database of the results.

A15. Burden Changes

This is a new information collection. Therefore, there are no changes or adjustments reported in A13 or A14.

A16. Tabulation, Publication Plans, Project Time Schedule

a) *Tabulation and analysis.* Results of the studies will be subjected to descriptive analyses, including frequencies and cross-tabulation of the attitude and behavior variables by demographic factors. As appropriate, analysis of variance (ANOVA), factor analyses, and multiple regression techniques will be employed.

b) *Publication.* A final report of the study procedures and results will be issued at the end of the data collection period, as specified in the contract. The results will be reported to the FDA Commissioner, and it is anticipated that the findings from these studies will be presented in FDA reports and in publications in scientific journals.

c) *Schedule.* Data collection will begin as soon as logistically possible after OMB approval is obtained. Data analysis will take approximately 2-3 months and reports will follow in 2-3 months following data analysis.

A17. Approval Not to Display OMB Expiration Date

We are not seeking approval to not display the OMB expiration date. The OMB approval number and expiration date will be displayed on the questionnaires.

A18. Exemptions to Certification Statement

We are not seeking any exemptions to the Certification Statement.