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Supporting Statement

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

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sample Selection

All respondents will be physicians able to speak and read English. The research will be undertaken by FDA through an existing contract with FDA's Center for Food Safety and Nutrition with a survey research organization (Synovate) for quick-response data collection. There will be a total of 900 interviews completed.

The 900 interviews will comprise 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. The sample will be stratified by practice type. It will consist of approximately one-half primary care physicians and one-half specialty care physicians who use medical products that have been the subject of recent emerging risk communications.

- The primary care physicians will include office-based family practitioners, general practitioners, general internal medicine practitioners, OB/GYNs, and pediatricians.
- The specialty care physicians will include office-based allergists, dermatologists, endocrinologists, nephrologists, certain oncologists, ophthalmologists, certain surgeons, psychiatrists, pulmonologists and rheumatologists. Physician specialties were chosen to provide a reasonable cross-section of specialists that use both drugs and medical devices that might have been the focus of relatively recent publicity concerning changed risk information.

The procedure for selection of the practice specialties is based on two goals. One goal is to ensure reasonable representation of physicians who have experience with the range of medical products (pharmaceuticals and devices) addressed by the survey. This range includes drugs, vaccines, blood, tissue, and cellular products, and medical devices which can range from implantable devices (stents, cardiac defibrillators, knee and hip replacements) to infusion pumps, surgical staplers and imaging equipment. However, there are relatively few practitioners in many of the specialties that address devices and blood products. If we start by selecting an initial sample that is proportional with respect to the different specialty areas, many of the specialties we wish to have represented will likely have a very small number of respondents included in the final sample. To ensure that we have reasonable representation of these specialties, we are proposing to initially contact equivalent numbers of randomly selected individuals in each specialty area. A second goal, however is to obtain valid population parameter estimates. To do this, we will weight the data such that the contribution to the final results of the different specialties reflects their representation in the population.

B2. Procedures for Collection of Information

The survey will be conducted by telephone using survey screener questions and an interview questionnaire. The questionnaire will take approximately 15 minutes to complete.

B3. Procedures to Maximize Response Rates

Physicians are exceptionally busy professionals who generally employ either receptionists, office managers or nurses as "gatekeepers" to screen mail and telephone contacts. Because physicians are considered a hard to reach survey population, three procedures, based on literature and experience, will be used to maximize the response rate for physician respondents:

(1) Prenotification letters for physicians. Literature has shown that "cold-calling" physicians for surveys has an extremely low chance of success. Such tactics are unlikely to get through the gatekeeper to the physician. We propose to prenotify physician respondents by letter with a fax-back return option (O'Rourke, 1999). Approximately two weeks before the telephone survey is scheduled to begin, the physicians sampled will be sent an FDA-prepared letter outlining the goals of the survey, sent by First Class mail in custom 9X12 flat envelopes marked as coming from FDA (a copy of the prenotification letter can be found in Attachment C). This letter describes the purpose of the research and will be signed by either the Commissioner of the Food and Drug Administration (FDA) or the Directors of the 3 medical product Centers within the FDA.

Prenotification of physicians is less likely than a general population sample to be biased by the number of physicians whose phone numbers are unlisted. Rather, by notifying the physician in advance of the survey, it presupposes that the physician's responses are not truly anonymous (i.e., the physician's address and name are known to the interviewer). In our estimation, however, the potential increase in response rate outweighs the risks of refusal on the basis of non-anonymity. To correct for this possibility, extra steps will be taken to reassure the physician respondents that their answers will be kept confidential.

(2) Callbacks. After the initial contact, up to 20 additional callbacks will be employed in an attempt to reach the physician. A negative response from the gatekeeper will not be accepted as a termination. Callbacks will be scheduled during different times of the day and days of the week. If the respondent is not available, an appointment for a callback will be made with the gatekeeper, and the respondent will be contacted at the designated appointment time. If it is not possible to schedule an appointment, the interviewer will leave a telephone number for the respondent to schedule an appointment to conduct the interview. Follow-up calls will be made by interviewers specially trained and experienced in refusal conversion.

(3) Incentives for physicians. Physicians are routinely paid an incentive for their participation in surveys (e.g., Kasprzyk et al., 2001; Tambor et al., 1993). The high salience of

the topic of medical product safety may not be enough to guarantee widespread survey participation. Physician respondents will be offered a $75 incentive for participation.

B4. Tests of Procedures

The contractor has reviewed the questionnaire. The questionnaire was also reviewed by individuals within FDA's Center for Food Safety and Applied Nutrition who are highly experienced with telephone survey design. Eight completed cognitive interviews were used as an initial test of procedures and understanding of terminology and questions. A number of questionnaire items were simplified or otherwise revised to respond to the feedback received in the cognitive interviews. The procedures will be further tested in up to 3 sets of 9 pre-tests each.

B5. Contacts

The contact individual is:

Nancy M. Ostrove, Ph.D., Director, Risk Communications, FDA 301-827-9279

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Attachment A

Questionnaire

Hello. I'm _____ with Synovate, calling on behalf of the United States Food and Drug Administration, the FDA. The FDA is conducting a survey about current issues related to physicians' use of risk information about medical products. We recently contacted your office with a letter regarding this survey. As discussed in the letter, we are offering a $75 incentive for about 15 minutes of your time. Your participation is voluntary, but is also extremely important to FDA in order for the survey results to be as valid and useful as possible. Your answers will be kept strictly confidential. We will not keep any record of your phone number, name, or address.

Is now a good time to talk with you?

S1. Yes [GO TO S3]

S2. No [SCHEDULE APPOINTMENT]

First, I'd like to ask you a few questions to help us classify your responses.

D1. In an average work week, do you provide direct care to patients at least half time? [IF NO, THANK AND TERMINATE]

D2. In what year did you graduate from medical school? _____

D3. In what type of practice setting do you have most of your contact with patients? Do you practice

a. mostly on your own
b. with a private group containing either physicians or other health care providers
c. in a staff model HMO practice such as Kaiser Permanente
d. in a clinic
e. in a hospital, or
f. in some other setting [SPECIFY] _____

D4. Thinking about prescriptions of all kinds, about how many prescriptions do you write in an average week, including hospital and institutional orders?

___ ___

D5. Now thinking about patients who have implanted devices such as pacemakers, joint replacements, stents, and the like, how many do you see in an average week?

___ ___

D6. Just to confirm, is your primary area of specialization _____ (insert from AMA Physician Masterfile)?

Yes [GO TO INTRO TO MAIN SURVEY]
No

D7. Which of the following categories best describes your primary area of specialization?

_____ [List depends on final sample determination]

Thank you. Today's interview is about how physicians get and use information about the risks of medical products in patient care. For the purpose of today's interview, assume such products include pharmaceuticals [far-ma-SOO-ti-kulz], vaccines, medical devices, blood, and cells and tissues used in

transplants or implants. Medical devices include both implantables, such as stents and orthopedic replacements, and common medical equipment.

[Section 1 – When to receive information and from what sources]

My first questions are about when and how you get **newly emerging** information about possible product risks. By this I mean information that comes out when products get used in medical practice or sometimes when they are studied to see if they work for new uses. This has happened recently, for example, with Avandia [uh-VAN-dee-uh], drug-eluting stents, and NSAIDS [N-sayds], including Vioxx [VIE-ox].

1. When would you like to get information about a newly emerging **serious** product problem that may cause hospitalization or a life-threatening situation?
    a. when there is an **initial suspicion** of a problem, but **before** a link is confirmed between the problem and the product;
    b. when there is a **reasonable link** between the problem and the product, but **before** the risk is included in official prescribing information; or
    c. **only** when there is a **firm recommendation** about how to manage the problem

2. When would you like to get information about a newly emerging product problem that is **less serious** but still might be annoying for your patients?
    a. when there is an **initial suspicion** of a problem, but **before** a link is confirmed between the problem and the product;
    b. when there is a **reasonable link** between the problem and the product, but **before** the risk is included in official prescribing information; or
    c. **only** when there is a **firm recommendation** about how to manage the problem

(3-16) I'm going to mention some possible sources for informing you of newly emerging risk information. I'd like you to tell me the extent to which you would trust each of these sources to give you truthful and unbiased information about a newly emerging medical product risk. Let's start with [SOURCE HERE – PRESENT IN RANDOM ORDER]. Would you trust [this source] very much, somewhat, not too much, or not at all to give you truthful and unbiased information about a newly emerging product risk? Next, what about …..

3. the medical and scientific literature
4. medical meetings
5. the official product information
6. the product's manufacturer, through representatives or letters
7. news in popular print, TV, or radio
8. your medical association or society
9. pharmacists
10. patients
11. the Food and Drug Administration
12. your State Board of Medicine
13. your State Health Department
14. practice-focused electronic sources like Medscape, WebMD, Epocrates
15. managed care plan provider web, electronic, or print materials
16. comparison sources like The Medical Letter

17. Are there other sources that you would be very likely to trust to give you truthful and unbiased information about a newly emerging medical product risk? (yes, no)
[IF YES] What is that? _____]

18-19. Assume you've already gotten information from a product's manufacturer or distributor about a **serious** newly emerging risk possibly caused by a pharmaceutical or medical device. [ROTATE 18 AND 19]

18. Would you also want to get a notice from the FDA if it contained **more details** about the risk?
Yes
No
Depends on product [VOL]
Don't know [VOL]

19. Would you also want to get a notice from the FDA if it contained **newer information** about the risk?
Yes
No
Depends on product [VOL]
Don't know [VOL]

20. [DO NOT ASK IF BOTH Q18 AND Q19 ARE "NO" or "DEPENDS ON PRODUCT"] Would you also want to get a notice from the FDA **even if it did not have additional details or newer information**? (yes, no, depends on product [VOL], Don't know [VOL])

21. What title or heading would be most likely to get you to read a notice about a possible problem with a medical product? _____

22-25. How useful to you would each of the following be if it was included in notices about newly emerging product risks? [NEW]
22. Would including product benefits explained so patients can understand them be very useful, somewhat useful, not too useful, or not at all useful?
23. Would including treatment recommendations from your medical society be very useful, somewhat useful, not too useful, or not at all useful?
24. Would mentioning non-risk associated alternatives you could use with your patients be very useful, somewhat useful, not too useful, or not at all useful?
25. Would including data about the risks of not treating the patients for the product's indicated health problem be very useful, somewhat useful, not too useful, or not at all useful?

26. What national newspaper do you read on at least a weekly basis? Do you read … [ROTATE ORDER; ACCEPT MULTIPLE RESPONSES]
a. New York Times
b. Wall Street Journal
c. Washington Post
d. Los Angeles Times
e. Chicago Tribune
f. Boston Globe

g. USA Today
h. Houston Chronicle
i. other [SPECIFY] _____
j. none [VOL]

[Section 2 – Impact of newly emerging risk information on patients and practice]

27. **In the past year**, has any patient called or visited you because they learned from someone or something **other than you** about a newly emerging risk with a prescription drug or device they use?
    Yes
    No [GO TO 38]
    Don't know [GO TO 38]

28. Now, think about the most recent patient this happened with and your relationship with that patient. Did the patient learning about the risk from somewhere other than you have a very positive effect, a somewhat positive effect, no effect, a somewhat negative effect, or a very negative effect on your relationship?

    Very positive effect
    Somewhat positive effect
    No effect
    Somewhat negative effect
    Very negative effect
    Don't know/refused [VOL]

(29-36) Did the fact that your patient got this risk information before the two of you discussed it: [ROTATE LIST]. Did it ….?

29. help, hinder, or not affect your subsequent discussions with your patient?
31. frighten, not frighten, or not affect your patient's feelings about using the product?
32. lead to the patient stopping use of the product **before** discussing doing so with you? yes or no?
33. lead to the patient telling you about a problem he or she was having with the product? yes or no?
34. lead to the patient distrusting your judgment about using the product? yes or no?
35. lead to the patient distrusting later recommendations you made about using the product? yes or no?
36. change how you subsequently prescribed the product for the patient? yes or no?
37. change how you subsequently prescribed the product for other patients? yes or no?

37. How typical was this incident compared with other times a patient heard from somewhere other than you about an emerging product risk? Was it very typical, somewhat typical, not too typical, or not at all typical?

[Section 3 – Use/awareness of Internet and electronic information sources]

Now I'd like to ask you about your use of the Internet and other electronic sources of newly emerging risk information. Remember that I'm still referring to the range of medical products from pharmaceuticals [far-ma-SOO-ti-kulz] to devices.

38. Do you use the Internet to look for information about newly emerging risks associated with the medical products you use in your practice? Yes or no?
    Yes
    No

39. Do you subscribe to any services or lists that e-mail you about newly emerging risks of **pharmaceuticals** [far-ma-SOO-ti-kulz] you use in your practice? Yes or no?
    Yes
    No

40. Do you subscribe to any services or lists that e-mail you about newly emerging risks of **medical devices** you use in your practice? Yes or no?
    Yes
    No

41. [ASK **ONLY** IF BOTH 39 AND 40 ARE **NO**] Would receiving newly emerging product risk information via e-mail be very helpful, somewhat helpful, not too helpful, or not at all helpful to you in your practice?

42. Before today, had you ever heard of **MedWatch**?
    Yes
    No [GO TO 44]

43. Can you tell me what company or organization sponsors MedWatch? [DO NOT READ; USE PRECODES]
    FDA
    American Medical Association/AMA
    American Academy of Family Physicians/AAFP
    Medscape/WebMD
    Epocrates
    private consortium
    Centers for Disease Control and Prevention/CDC
    consumer group or groups
    managed care/Kaiser Permanente/Blue Cross-Blue Shield
    medical product manufacturers/BIO/PhRMA
    other [specify] _____
    Don't know

44. Have you ever been to the FDA's Internet site? Yes or no?
    Yes
    No [GO TO 53]
    Maybe/not sure [VOL] [GO TO 53]
    Don't know/refused [GO TO 53]

45. Do you typically visit the FDA's Internet site daily, weekly, or monthly, or do you visit it yearly or less?
    Daily
    Weekly
    Monthly
    Yearly or less

46. What kind of job does the FDA's Internet site do in providing information useful to you in your clinical practice. Does it do an excellent, good, only fair, or poor job?

47. Have you ever looked on the FDA's Internet site for information about a newly emerging risk for a **specific prescription medicine**?
    Yes
    No [GO TO 49]

48. In your opinion, is it very difficult, somewhat difficult, not too difficult, or not at all difficult to find information about a **specific prescription medicine** on the FDA's Internet site?

49. Have you ever looked on the FDA's Internet site for information about a newly identified risk for a **specific medical device**?
    Yes
    No [GO TO 51]

50. In your opinion, is it very difficult, somewhat difficult, not too difficult, or not at all difficult to find specific information about a **specific medical device** on the FDA's Internet site?

51. Have you ever read the information sheets on the FDA's Internet site that are written specifically for health care professionals about prescription medicines?
    Yes
    No [GO TO 53]
    Don't know [GO TO 53]

52. Generally, how useful are these information sheets for you? Are they very useful, somewhat useful, not too useful, or not at all useful?

53. Have you ever seen an FDA "Public Health Notification" regarding a medical device?
    Yes
    No [GO TO 62]
    Maybe/not sure [VOL]
    Don't Know [GO TO 62]

How did you get this notification? Did you … (yes or no for each)

54. get a public health notification mailed to you? yes or no?
55. get a public health notification faxed to you? yes or no?
56. get a public health notification e-mailed to you? yes or no?
57. see a public health notification on the FDA's Internet site? yes or no?
58. see a public health notification on another organization's Internet site? yes or no? [IF YES, ASK 60]

59. get a public health notification from another organization in some other way? yes or no? [IF YES, ASK 61]

60. [ASK IF Q58=YES] And which organization was that? _____

61. [ASK IF Q59=YES] And which organization was that?
_____

[Section 4 – Reporting adverse events and product problems]

I'd like to switch gears now and ask you about sharing information about problems with pharmaceuticals [far-ma-SOO-ti-kulz] and medical devices your patients use.

62. In the past 12 months, have you reported to **anyone** an adverse event or problem a patient had with a pharmaceutical [far-ma-SOO-ti-kulz] or a medical device?
    Yes
    No [GO TO 64]

63. Thinking about the **most recent time this happened**, to whom did you report the adverse event or problem? [DO NOT READ; USE PRECODES; ACCEPT MULTIPLE RESPONSES] Anyone else?
    product's manufacturer
    FDA
    hospital, clinic, or health plan pharmacist
    the P&T (Pharmacy & Therapeutics) group at the hospital or health plan
    hospital, clinic, or health plan administration
    malpractice insurance provider
    local pharmacist
    medical examiner (ME)
    CDC (Centers for Disease Control and Prevention)
    other [SPECIFY] _____
    Don't Know/Can't remember

64. Now thinking about when you have **ever** reported an adverse event or product problem, what is the **typical** way you report these? Have you typically…?
    a. **Told** someone face to face?
    b. **Called** someone on the telephone
    c. **Faxed** a form to someone
    d. **Mailed** a form to someone
    e. **E-mailed** a form to someone
    f. Or reported some other way [SPECIFY _____]
    Do not report/have never reported [VOL]
    Don't know/no answer [VOL]

65. Typically, who have you notified? [DO NOT READ; USE PRECODES]
    product's manufacturer
    FDA
    hospital, clinic, or health plan pharmacist

the P&T (Pharmacy & Therapeutics) group at the hospital or health plan
hospital, clinic, or health plan administration
malpractice insurance provider
local pharmacist
medical examiner (ME)
CDC (Centers for Disease Control and Prevention)
other [SPECIFY] _____
DK/can't remember

66. When was the most recent time you reported an adverse event or product problem?
    a. Within the last year
    b. Between 1 and 2 years ago
    c. Between 3 and 5 years ago
    d. Over 5 years ago
    DK/Can't remember [VOL]

67. Before today, did you know that health care providers can report product problems or adverse events directly to the FDA by telephone?
    Yes
    No
    Don't know/no answer [VOL]

68. Before today, did you know that FDA provides a special form for reporting adverse events or problems with drugs or medical devices directly to FDA?
    Yes
    No [GO TO 73]
    Don' t know/No answer [GO TO 73]

69. Do you know how to get this form?
    Yes
    No

70. Have you ever used this form to notify FDA about a drug or device adverse event or product problem?
    Yes
    No [GO TO 73]
    Don't know/can't recall [GO TO 73]

71. How easy or difficult was it to use this form? Was it
    Very easy [GO TO 73]
    Somewhat easy
    Somewhat difficult
    Very difficult
    Don't know/can't recall [GO TO 73]

72. What problems did you have with the form? [DO NOT READ; USE PRECODES; ACCEPT MULTIPLE RESPONSES]
    Too long

Too complicated
Too cumbersome/unwieldy
Needed too many answers
Couldn't follow the logic
Too hard to submit
Other [SPECIFY] _____
None/no significant problems

73. When, if ever, would you **not** report a pharmaceutical or device adverse reaction or product problem? [DO NOT READ] Anything else? ….

Never

_____
_____
_____

That's all the questions I have for today. Is there anything else you'd like to tell me about these topic areas?

Attachment C

Prenotification Letter for Physician Survey

HHS/FDA LETTERHEAD

Month and Date, 2007

Dear Colleague,

As we review the Food and Drug Administration's (FDA) activities, it is crucial that we consider the needs of practicing physicians like yourself. In the next few weeks, you will be getting a call from a representative of Synovate, who will ask you to participate in a telephone survey they are conducting on behalf of the FDA. This survey concerns your use of risk information about medical products. The results of this survey will be used to help the FDA focus its communication efforts about medical product risks and benefits.

You are one of a small group of physicians, drawn from a national database, who we are asking to participate in our survey. For us to be able to draw valid conclusions, it is vital that we obtain your cooperation. However, your participation is purely voluntary. The FDA will not know the choice you make concerning participation. Should you choose to participate, your responses will be kept completely confidential. It will not be possible for the FDA to link you, personally, with any of the questionnaire responses.

The survey will take about 15 minutes. The results will be published on the FDA's website as well as in other professional publications. We would also like to offer you a $75 honorarium as a token of our appreciation for your time. We hope you will help us in our efforts.

Thank you very much for your participation.

Sincerely,

Andrew von Eschenbach, M.D.
Commissioner, Food and Drug Administration