### 2024 Current Fiscal Year Report: Risk Communication Advisory

## Committee Report Run Date: 04/23/2024 06:58:45 AM 1. Department or Agency 2. Fiscal Year

1. Department or Agency		<b>2.</b> FI	2. Fiscal Year			
Department of H Services	artment of Health and Human <i>r</i> ices		2024	2024		
3. Committee or Subcommittee			3b. 0 No.	3b. GSA Committee No.		
Risk Communication Advisory Committee		visory	3195	31951		
4. Is this New During 5. Current 6. Expected 7. Expected						
Fiscal Year?	-		newal Date	-		
No	07	/17/2009				
8a. Was Terminated During8b. Specific Termination8c. Actual Term DateFiscalYear?Authority						
No						
9. Agency Recommendat FiscalYear	ion for N	ext	gislation Terminate?	10b. Legislation Pending?		
Terminate		Yes		Pending		
<b>11. Establishment Authority</b> Statutory (Congress Created)						
	0110710001	Unity Statute				
12. Specific		13.	14.			
		-	14.	14c.		
12. Specific		13.	14.			
12. Specific Establishment		13. Effective Date	14. Commitee	14c.		
12. Specific Establishment Authority	bb-6	13. Effective Date 09/27/2007	14. Commitee Type Continuing	14c. Presidential? No		
<b>12. Specific</b> Establishment Authority 21 U.S.C. 360bl	bb-6	13. Effective Date 09/27/2007	14. Commitee Type Continuing	14c. Presidential? No		
<ul> <li>12. Specific</li> <li>Establishment</li> <li>Authority</li> <li>21 U.S.C. 360bl</li> <li>15. Description</li> <li>Advisory Board</li> <li>16a. Total</li> <li>Number of</li> <li>Reports</li> <li>17a.</li> </ul>	bb-6 a <b>of Com</b> i No Rep this Fiso	13. Effective Date 09/27/2007 mittee Scien orts for calYear	14. Commitee Type Continuing	14c. Presidential? No		
12. Specific Establishment Authority 21 U.S.C. 360bl 15. Description Advisory Board 16a. Total Number of Reports 17a. 0 17b. Cl	bb-6 of <b>Com</b> No Rep this Fiso osed 0 1	13. Effective Date 09/27/2007 mittee Scien orts for calYear	14. Commitee Type Continuing	14c. Presidential? No al Program		

**Current Next** 

	FY	FY
18a(1). Personnel Pmts to	\$0.	00\$0.00
Non-Federal Members		
18a(2). Personnel Pmts to	¢0	00\$0.00
Federal Members	ψ0.	00φ0.00
18a(3). Personnel Pmts to	ድሳ	00\$0.00
Federal Staff	<b>Ф</b> О.	00 \$0.00
18a(4). Personnel Pmts to	ድር	00 00 00
Non-Member Consultants	<b>Ъ</b> О.	00\$0.00
18b(1). Travel and Per Diem to	ድር	00 00 00
Non-Federal Members	<b>Ъ</b> О.	00\$0.00
18b(2). Travel and Per Diem to	ድብ	00\$0.00
Federal Members	<b>Ф</b> О.	00 \$0.00
18b(3). Travel and Per Diem to	ድብ	00 00 00
Federal Staff	<b>Ф</b> О.	00\$0.00
18b(4). Travel and Per Diem to	ድር	
Non-member Consultants	\$0.00\$0.00	
18c. Other(rents,user charges,	ድር	
graphics, printing, mail, etc.)	\$0.00\$0.00	
18d. Total	\$0.	00\$0.00
19. Federal Staff Support Years	•	~~ ~ ~ ~
(FTE)	0.	00 0.00

#### 20a. How does the Committee accomplish its purpose?

Members' comments and discussion provide advice to the Agency on improving communications practices, from both a basis of scientific research and practical experience, in matters ranging from specific types of agency communications to more general strategies and research needs, in order to help the agency accomplish its goal of improving patient and consumer safety by providing risk-benefit information that is clear, timely, and usable by the audience. The meetings also facilitate the RCAC purpose of interactive sharing of information

between the FDA and the public.

## 20b. How does the Committee balance its membership?

The RCAC consists of 15 voting members including the Chair. Members are selected among authorities in fields such as risk communication, social marketing, health literacy, and other relevant areas. Some members will be selected to provide experiential insight on the communications needs of various groups who use FDA-regulated products such as patients, healthcare professionals, consumer or patient advocacy organizations. Depending on the topic, the commissioner or designee may select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. FDA will give close attention to distribution with respect to members' geographic region, minority status, and sex, so long as the effectiveness of the Committee is not impaired.

## 20c. How frequent and relevant are the Committee Meetings?

The committee did not meet in FY-22 and is considered Administrative Inactive.

## 20d. Why can't the advice or information this committee provides be obtained elsewhere?

FDA strives to communicate with many audiences using many instruments, but in the past not all were developed or evaluated in ways consistent with established best practices in risk communication. The RCAC is necessary in order to bring expertise on current research and established best practices to the Agency, to help the agency interact with the public for more effective risk communication. This need was recognized both in the Congress (HR 3580) and the National Academies' Institute of Medicine (The Future of Drug Safety, recommendation 6.1).

20e. Why is it necessary to close and/or partially closed committee meetings? N/A

#### 21. Remarks

This committee is Administratively Inactive as the committee has completed the work that was required by the originating statute.

#### **Designated Federal Officer**

Ashlee N Janusziewicz DFO

#### Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Risk Communication Advisory Committee supports FDA's strategic priorities by providing expert advice on FDA strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products, review and evaluate scientific research relevant to risk communication, and facilitate the interactive sharing between FDA and the public of information on risks and benefits of FDA-regulated products.

## What are the most significant program outcomes associated with this committee?

	Checked if
	Applies
Improvements to health or safety	$\checkmark$
Trust in government	$\checkmark$
Major policy changes	$\checkmark$
Advance in scientific research	$\checkmark$
Effective grant making	
Improved service delivery	
Increased customer satisfaction	
Implementation of laws or regulatory	1
requirements	
Other	

#### **Outcome Comments**

N/A

#### What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	$\checkmark$
Under \$100,000	
\$100,000 - \$500,000	
\$500,001 - \$1,000,000	
\$1,000,001 - \$5,000,000	
\$5,000,001 - \$10,000,000	
Over \$10,000,000	
Cost Savings Other	

#### **Cost Savings Comments**

The utilization of the Risk Communication Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical, scientific and communications experts not otherwise available to the Agency and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

# What is the approximate <u>Number</u> of recommendations produced by this committee for the life of the committee?

188

#### Number of Recommendations Comments

The committee made 188 recommendations from FY03 through FY21.

## What is the approximate <u>Percentage</u> of these recommendations that have been or will be <u>Fully</u> implemented by the agency?

20%

#### % of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

# What is the approximate <u>Percentage</u> of these recommendations that have been or will be <u>Partially</u> implemented by the agency?

#### % of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

## Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes 🗹 No 🗌 Not Applicable 🗌

#### Agency Feedback Comments

Feedback is usually provided. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

## What other actions has the agency taken as a result of the committee's advice or recommendation?

#### Checked if Applies

Reorganized Priorities	✓
Reallocated resources	
Issued new regulation	
Proposed legislation	
Approved grants or other payments	
Other	✓

#### **Action Comments**

The committee does not advise on resource allocation, but prioritization may be reflected in resource allocation. The other actions boxes above that are checked applicable are showing that the Agency is actively engaged in developing internal strategy, process, and capacity to implement recommendations more fully, but none of this is complete at this time. The boxes above that are blank are, to date, inapplicable.

#### Is the Committee engaged in the review of applications for grants? No

## Grant Review Comments N/A

#### How is access provided to the information for the Committee's documentation?

Checked if Applies
$\checkmark$

Access Comments

N/A