foi

5210671

A

5210671 A

CDC Meeting: 03/26/1997 Minutes and Agenda Regarding Thalidomide

5210671 4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

OCT 17 2003

October 3, 2003

Rachel M. Johnson
FOI Services, Inc.
11 Firstfield Road
Gaithersburg, Maryland 20878-1704

Dear Ms. Johnson:

This letter is in response to your Freedom of Information Act (FOIA) request of August 14.

Enclosed are documents you requested.

In accordance with the Department's implementing regulations, 45 CFR Part 5, a fee of is assessed (see enclosed invoice). Please follow mailing instructions on the invoice or your payment may not be credited.

Sincerely yours,

Lynn Armstrong
CDC/ATSDR FOIA Officer
Office of Communication
(404) 639-7270
Fax: (404) 639-7395

Enclosures

03-0850

Case No.: 03-0850

Date of Invoice: 10/03/03

Invoice of Fees for Freedom of Information Act Services

CDC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Requester's Name, Organization, and Address:

Rachel Johnson
FOI Services, Inc.
Fairhaven, MD 208 78

Category: [✓] I [ ] II [ ] III

Instructions:

1. Please write the case number shown at the top of this form on your check or money order.
2. Make your check or money order payable to: United States Department of Treasury.
3. Return one copy of this form with your remittance.
4. Mail to: Centers for Disease Control and Prevention, FOIA Office, 1600 Clifton Rd., NE, MS D54, Atlanta, GA 30333
5. Payment is due within 30 days from the date of this invoice. Interest will be charged after the due date.

Service			No. of Items or Hours	Price per Item or Hour	Subtotal	Allowance (if applicable)	Total
Reproduction	Standard Pages (8 1/2 x 11) or (8 1/2 x 14)		30				
	Other Reproduction						
Search Costs	Rate 1 (GS 1-8)			$18.00/hr			
	Rate 2 (GS 9-14)		2	$36.00/hr	$72.00		$72.00
	Rate 3 (GS 15 & above)			$64.00/hr			
Review Costs	Rate 1 (GS 1-8)			$18.00/hr			
	Rate 2 (GS 9-14)			$36.00/hr			
	Rate 3 (GS 15 & above)			$64.00/hr			
Computer Costs	Machine Time, Materials						
	Operator's Time or Search Time	Rate 1		$18.00/hr			
		Rate 2		$36.00/hr			
		Rate 3		$64.00/hr			
Certification				$10.00/ea.			
Special Mailing Charges							
				Pay Total of →			#

Person Preparing Invoice: K Flan

Phone No.: (404) 639-7270

Notes

CDC 0.1227
Rev. 5/2001

PREVENTING BIRTH DEFECTS DUE TO THALIDOMIDE EXPOSURE

Sheraton Colony Square Hotel
Atlanta, Georgia

March 26, 1997

Birth Defects and Genetic Diseases Branch
Centers for Disease Control and Prevention

Denise Webster
writer/editor

PREVENTING BIRTH DEFECTS DUE TO THALIDOMIDE EXPOSURE

Sheraton Colony Square Hotel
Atlanta, Georgia
March 26, 1997

Dr. Dixie Snider, Associate Director for Science, CDC, welcomed the participants.

Dr. Snider gave a synopsis of the history of Thalidomide and the role it played in changing the way drugs are approved for use in the United States. He stated that Thalidomide is used currently for the treatment of certain autoimmune disorders such as systemic lupus, rheumatoid arthritis, HIV, and for leprosy. There is concern over the use of Thalidomide in Brazil, where it is readily available as an over the counter drug, since there appears to be little evidence that its use is discouraged in pregnant women.

Dr. Snider stressed that if thalidomide is approved for use in the U.S., there must be strategies in place to reduce the risk of exposure of pregnant women to the drug. The goal is to avoid and/or reduce birth defects from all teratogenic drugs.

After this meeting, CDC will publish its written guidelines in the Morbidity and Mortality Weekly Report (MMWR) sometime this coming fall. Today's participants will have the opportunity to review those guidelines, and comment on them, prior to publication.

Assessment of Roche's Accutane Pregnancy Prevention Program - Dr. Allen Mitchell, Professor of Epidemiology and Pediatrics, Boston University

In the Fall of 1988, Roche Laboratories developed and implemented a Pregnancy Prevention Program for physicians, and women who were taking the drug Accutane. This education program included an information package for physicians, a comprehensive patient consent form, and a blister pack with an explicit warning against taking the drug while pregnant. Patients were strongly encouraged to participate in a voluntary survey, to judge compliance with the program.

Enrollment opportunities are provided through physicians, the medication package, and a toll-free telephone number, and women are paid $10 upon enrollment. Follow-up interviews are conducted by phone and mail. Study results were published in the New England Journal of Medicine in Fall of 1995.

Survey results showed that the understanding of the need to avoid pregnancy while on Accutane, and the understanding of birth defects caused by Accutane, were high. The observation that 78% of women waited for the results of pregnancy tests before taking Accutane prompted a change in the package warnings, and subsequently 85% reported waiting for test results prior to starting the drug. The self-selected participants tended to be well educated, and it is unclear whether they are

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.