

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

ARTHUR RAY BOWLING, ET AL.,	:	
	:	No. C-1-91-256
PLAINTIFF,	:	
	:	
V.	:	JUDGE HERMAN J. WEBER,
	:	SENIOR JUDGE
PFIZER, INC. ET AL.,	:	
	:	
DEFENDANT.	:	

NOTICE OF FILING OF THE TWENTY-THIRD REPORT OF THE  
SPECIAL MASTERS/TRUSTEES COVERING PERIOD  
FROM MAY 23, 2005 TO NOVEMBER 23, 2005

NOTICE IS HEREBY GIVEN to all counsel of record that the TWENTY-THIRD REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING PERIOD FROM MAY 23, 2005, TO NOVEMBER 23, 2005, is hereby filed with the Court.

Respectfully submitted,

*Nancy A. Lawson*

Nancy A. Lawson (0012699)  
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Cincinnati, OH 45202  
(513) 977-8200  
Attorney for  
Special Masters/Trustees

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this Notice of Filing of the Twenty-Third Report of the Special Masters/Trustees Covering Period from May 23, 2005, to November 23, 2005, has been hand delivered to those in Cincinnati and Federal Expressed to those outside Cincinnati this **23rd** day of **November, 2005**.

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Fay E. Stilz, Esq.  
Waite, Schneider, Bayless & Chesley Co., LPA  
1513 PNC Tower  
5 West Fourth Street  
Cincinnati, OH 45201

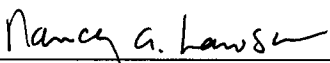
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\_\_\_\_\_  
Nancy A. Lawson

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

IN RE: : Case No. C-1-91-256  
BOWLING-PFIZER LITIGATION : Judge Herman J. Weber,  
: Senior Judge

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TWENTY-THIRD REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM MAY 23, 2005 TO NOVEMBER 23, 2005

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SPECIAL MASTERS/TRUSTEES

Hon. Robert L. Black, Jr.  
Peter J. Strauss, Esq.

**AGENDA**

**TWENTY-THIRD REPORT OF THE SPECIAL MASTERS/TRUSTEES**

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 8, 2005  
10:00 A.M.

Hon. Herman J. Weber, Senior Judge

1. Introductory remarks by Judge Weber.
2. Report of the Special Masters/Trustees.
3. Comments from Counsel:
  - Class Counsel.
  - Counsel for Defendants.
4. Questions and comments from those in attendance.
5. Request for date of next report of Trustees.
6. Closing remarks of Judge Weber.

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- A. Twenty-Third Report of the Special Masters/Trustees
  
- B. Appendices to Court Report
  - 1. Summary of Supervisory Panel meeting from October 31, 2005 through November 2, 2005.
  - 2. Schedule of ongoing research projects.
  - 3. "Hit Report" regarding the Supervisory Panel's Website.
  - 4. Unaudited balance sheet as of October 31, 2005 and an unaudited statement of income and funds balance for the ten months ended October 31, 2005.
  - 5. Independent Auditors' Report for the year ended December 31, 2004.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

IN RE: : Case No. C-1-91-256  
BOWLING-PFIZER LITIGATION : Judge Herman J. Weber,  
Senior Judge

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**TWENTY-THIRD REPORT OF THE SPECIAL MASTERS/TRUSTEES**

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To the Honorable Herman J. Weber, Senior Judge, United States  
District Court:

Your Special Masters/Trustees respectfully present their  
twenty-third periodic report, covering activities from May 23, 2005  
to November 23, 2005. This report is submitted fifteen days prior  
to the status hearing before the Court scheduled for December 8,  
2005.

**I. PATIENT BENEFIT FUND**

A. Supervisory Panel. The Supervisory Panel met from October  
31, 2005 through noon on November 2, 2005 in Cincinnati, Ohio. The  
entire panel: Joseph Defauw, Donald Harrison, Michel Ibrahim, Tom  
Ivey, Lewis Kuller, Arthur Weyman and David Miller attended the  
meeting. The Trustees, Peter Strauss and Judge Robert Black along

with the Claims Administrator, Wayne Smith, and the Trustees' Counsel, Nancy Lawson and David Malone, also attended. Class Counsel, Fay Stiliz, John Johnson, and Jim Capretz, along with Pfizer Counsel, Alan Goott attended the meeting on November 1, 2005.

The Panel voted to continue the studies of ACES, BioQuantetics, and Michigan State and to maintain its continued close scrutiny of these research projects to ensure that the milestones set forth in the research protocols and the continuing operation plan are being met. The Panel approved the proposal of ACES, "Passive Acoustic Detection of Implanted BSCC Heart Valves" with the provision that revisions to the proposal will be made to provide additional details of study activities, more refined milestones and a reduced budget. The Panel also voted to continue developing a protocol for testing patients using a diagnostic device(s). A subcommittee for that purpose was formed which includes: Dr. Ivey, Dr. Kuller, Dr. Ibrahim, Dr. Harrison, Dr. Brookmeyer and David Miller.

The Panel discussed a revision of the Guidelines and expects to have the revisions completed by the first quarter of 2006. The Panel agreed to meet with Counsel after it approves a draft revision to the Guidelines in order to discuss those revisions, the rationale for them and to obtain the comments of Counsel prior to submitting the final version of recommended Guidelines to the

Court.

A copy of the summary letter of the Supervisory Panel meeting is attached to this Report as Appendix 1.

B. Guidelines. The Panel will be completing revisions to the Guidelines in early 2006 as discussed above.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached Appendix 2. A new format for this report is being used to comply with the Court's Order for a monthly financial report of the Panel's ongoing projects.

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, three implantees who may qualify for replacement surgery have been imaged.

E. Repository. The Supervisory Panel continues to maintain a publicly accessible repository of certain documents and information concerning the BSCC heart valve. The repository contains hard copy printouts of various items including, but not limited to, certain reports on the status and results of research sponsored by the Supervisory Panel, minutes of meetings of the Supervisory Panel, a bibliography of published literature regarding the BSCC heart valves, certain unpublished reports prepared by Dr. Brookmeyer of his statistical analysis, the Bowling Settlement Agreement, and other information. The repository is currently located at the Trustees' office.



In addition, the Trustees have made many of the documents in the repository available electronically in a database which can be accessed through the internet at [www.bowling-pfizer.com/repository](http://www.bowling-pfizer.com/repository). Individuals are able to search for information using descriptive words. Some of the information, such as published articles, are not available for review online due to copyright and other intellectual property concerns. To access the online repository, an individual need only contact the Trustees' office for the website location and a password. The Trustees have placed an announcement on its website providing class members and other interested individuals with information about the electronic database.

F. Website. The Supervisory Panel's website continues to be found at [www.bowling-pfizer.com](http://www.bowling-pfizer.com). It provides basic information on the parties involved (biographies, addresses, telephone numbers, email, etc.), certain orders of the Court including the 2003 Amended Guidelines, a copy of the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information.

As noted above, an announcement has been placed on the website explaining that many of the documents contained in the document repository are now available on-line. Further, a copy of the most recent "hit report" of the Supervisory Panel's website is attached to this Report as Appendix 3.

G. Valve Replacement Surgery Claims and Fracture Claims.

The Claims Administrator continues to receive and process claims for valve replacement surgery and outlet strut fracture. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits.

Since the date of the last Trustees' report on May 23, 2005, Pfizer Inc. paid \$220,000 US plus 175,075 Japanese Yen for qualifying strut fracture benefits for a claim processed by the Claims Administrator. These benefit payments relate to a claim for an outlet strut fracture that occurred prior to May 23, 2005.

The total number of qualified claims received from the beginning are: 95 (72 foreign) qualified outlet strut fracture claims and 137 (55 foreign) qualified valve replacement surgery claims including 38 (16 foreign) qualified single leg fracture claims.

On June 3, 2005 MedicAlert mailed to 2,674 BSCC heart valve implantees a notice to register Class Members that was prepared by Class Counsel. In response to the mailing there have been 255 newly registered Class Members. Three of these Class Members potentially qualify for valve replacement surgery benefits under the Supervisory Panel's current guidelines. A letter was sent to each of the three Class Members advising them of their status and outlining the benefits provided under the Settlement.

The office of the Claims Administrator continues to fulfill requests to calculate estimated annual fracture rates under the 2003 Amended Guidelines. In addition, the office of the Claims Administrator continues to respond to other inquiries from and on behalf of Class Members.

## **II. FINANCIAL INFORMATION**

At October 31, 2005, the total balance of cash and cash equivalents was \$28,018,300. This amount takes into account net interest earned from January 28, 1992 through October 31, 2005 in the aggregate amount of \$24,085,750. The final annual payment of \$6,250,000 due from Pfizer/Shiley under the Settlement was received on September 27, 2005.

Attached as Appendix 4 are the following: an unaudited balance sheet as of October 31, 2005 and an unaudited statement of income and funds balance for the ten months ended October 31, 2005 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2005 through December 31, 2005).

Attached as Appendix 5 is a copy of the Independent Auditors' Report for the year ended December 31, 2004.

## **III. COMMUNICATIONS**

Communications remain open, whether with physicians, Class Members, other BSCC heart valve implantees, Class Counsel, Special Counsel, Defendant's Counsel, or Counsel for Public Citizen.

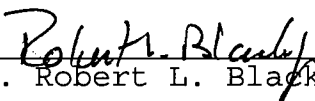
**IV. APPROVALS**


Your honor, the Special Masters/Trustees request that the Court:

- Approve this Report, and
- Approve, or provide guidance with respect to, each of the Appendices to this Report, and
- Provide guidance with respect to any duty of the Special Masters/Trustees, and
- Fix the date for the next Report.

Respectfully submitted,

Dated: November 23, 2005

  
\_\_\_\_\_  
Hon. Robert L. Black, Jr.

  
\_\_\_\_\_  
Peter J. Strauss, Esq.

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**APPENDIX 1**

TRUSTEES FOR THE BOWLING-PFIZER  
HEART VALVE SETTLEMENT FUNDS

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525 VINE STREET, SUITE 2300 – CINCINNATI, OHIO 45202-3124  
TELEPHONE: 513/421-4415 OR 800/977-0779 FAX: 513/421-7696

TRUSTEES:

November 11, 2005

HON. ROBERT L. BLACK, JR.  
PETER J. STRAUSS, ESQ.

Alan F. Goott, Esq.  
Kaye Scholer LLP  
425 Park Avenue  
New York, NY 10022-3598

Fay E. Stilz, Esq.  
Waite, Schneider, Bayless & Chesley  
1513 Fourth & Vine Tower  
One West Fourth Street  
Cincinnati, OH 45202

Dear Alan and Fay:

The following is a summary of the Supervisory Panel meeting conducted at Cincinnati, Ohio on October 31 through November 2, 2005.

**October 31.**

The entire Panel (Joseph Defauw, Donald Harrison, Michel Ibrahim, Tom Ivey, Lewis Kuller, Arthur Weyman and David Miller) met from 8:00 a.m. to 3:00 p.m. to hear and discuss various epidemiology reports and how they may impact the Guidelines for eligibility for surgical benefits. The Panel was joined by Ron Brookmeyer, Bill Blot and Eugene Blackstone in this session. Also present were Peter Strauss, Wayne Smith, Nancy Lawson and David Malone.

The entire Panel then heard updates and discussed the progress of ACES, BioQuantetics and Michigan State University on their diagnostic device development. We were joined by Mark Schafer for these discussions. Also present were Peter Strauss, Nancy Lawson and David Malone.

**November 1.**

This session included the Supervisory Panel, Ron Brookmeyer, Bill Blot and Mark Schafer, the Honorable Robert Black and Peter Strauss, Wayne Smith, Nancy Lawson, David Malone, Fay Stilz, Alan Goott, John Johnson and Jim Capretz and several investigators as noted below. The meeting was divided into three sessions, Imaging and

Acoustics, Guidelines and Epidemiology, and a meeting between Counsel and the Panel. This is an outline of those sessions.

#### Imaging and Acoustics Session

30 minute Status Reports on progress and status of work followed by a 20 minute Q & A on each project:

Jeff Crompton, ACES

Edmond Rambod, BioQuantetics

Satish Udpa, Michigan State University

An in-depth Question and Answer session and discussion on the overall progress of the "Sound" investigators in developing a diagnostic device for Class members. The discussion was led by Mark Schafer regarding the status of these projects, progress made, current status, challenges and next steps.

#### Guidelines and Epidemiology Session

BSCC research database update and a review of the current Guidelines by Ron Brookmeyer.

The accuracy of the BSCC research database (comparison to PSU database) by Bill Blot.

Long term survival following replacement of BSCC valves in Sweden by Michel Ibrahim.

The International Explant Study by Bill Blot.

The STS surgical mortality data by Tom Ivey.

The Cleveland Clinic follow up study by Eugene Blackstone.

The Quality of Life study by Bill Blot.

#### Meeting with Counsel and the Panel.

A financial status report on the activities of the Panel was presented by Wayne Smith and David Miller and copies were provided.

Alan Goott made several comments regarding the possible revision to the Guidelines. He suggested some flexibility in the Class members' eligibility for surgical benefits may be

appropriate. He also raised the issue of single leg fracture detection efforts and, if a diagnostic device successfully developed, how the Panel will incorporate this knowledge of the status of the valve into the Guidelines or the information it presents to patients and their doctors.

James Capretz surveyed 10 Class members regarding participation in a non-invasive diagnostic device test and 1 indicated they would be interested.

John Johnson spoke with 5 Class members and the consensus is they want the Panel to give them the best information available about the valve and what the patient should do with respect to their valve. They want any action taken by them regarding their valve paid for by the Settlement.

John Johnson recommends the Panel remove the factor of age from the Guidelines. He indicated he has reviewed the manufacturing records of the 33 recently fractured valves and identified some issues he wants the Panel to review and consider. He will forward the information he developed to David Miller.

### November 2.

The entire Panel met to discuss the information presented throughout the meetings on October 31 and November 1 and to take action on several matters. Also present at this session were Judge Black, Peter Strauss, Bill Blot, Gene Blackstone, Wayne Smith, Nancy Lawson and David Malone.

1. The Panel decided to continue the studies of ACES, BioQuantetics and Michigan State University and to maintain its close scrutiny of these research groups to ensure the milestones set forth in the research protocols and the Continuing Operation Plan are being met. Additional evaluation of these projects by the entire Panel will occur at the discretion of the Chairman.
2. The Panel approved the proposal of ACES, "Passive Acoustic Detection of Implanted BSCC Heart Valves" with the understanding that revisions to the proposal will be made to provide additional details of study activities, more refined milestones and a reduced budget. The revisions will be worked out with the Imaging and Acoustics Committee, Dr. Crompton and David Miller.
3. The Panel agreed it should continue the work outlined in the Continuing Operation Plan on developing a protocol for testing patients using a diagnostic device(s) and what the patients will be told about the testing outcome. A group of Tom Ivey, Lewis Kuller, Michel Ibrahim, Don Harrison, Ron Brookmeyer and David Miller has been established.
4. The Panel decided the outlet strut fracture rate threshold chart should be based upon continuous year to year points, not the 5 year groupings which are in the current Guidelines.



5. The Panel decided to use the Cleveland Clinic 90 day follow up data of the incidence of death or stroke of NYHA Class I and II patients over the 10 year period of 1995 to 2005 in re-calculating the formulas contained in the Guidelines.
6. The Panel decided to provide a buffer zone to Class members who potentially qualify for surgical benefits under the Guidelines. The buffer zone is to provide the Class member additional time to be eligible for surgical benefits beyond the time the person will "age out". The buffer zone will be equal to 10% of the remaining life expectancy of the person calculated at age of the person at the time the Guidelines are revised<sup>1</sup>. The remaining life expectancy will be based upon life expectancy of BSCC patient cohort studies done in the United States, United Kingdom and the Netherlands.
7. The Panel is considering revising some of the language in the Guidelines to more accurately describe a "significantly experienced facility" as outlined in Section IV, Part B.
8. The Panel agreed to meet with Counsel after it approves a draft revision to the Guidelines to discuss those revisions, the rationale for them, and to obtain the comments of Counsel prior to submitting the final version of recommended changes to the Court.

Please let me know if you have any comments or questions about this synopsis. Thank you.

Respectfully submitted,



David E. Miller  
Chairman Supervisory Panel

cc: Brian Wolfman, Esq.

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<sup>1</sup> For example, a Class member is age 40 and potentially qualifies to receive surgical benefits under the revised Guidelines. Assume the Class member would age out in one year and the remaining life expectancy of the person is 30 years. This Class member would have a buffer zone of an additional 3 years in which remain eligible for surgical benefits. In this example, the Class member would have a total of 4 years to remain eligible for surgical benefits.

**APPENDIX 2**

**Trustees for the Bowling-Pfizer Heart Valve Settlement Funds  
Supervisory Panel Research Projects Ongoing At January 31, 2005**

Continuing Operation Plan Ongoing Projects	Termination Date	Balance 1/31/2005	Billed 2/1/2005 10/31/2005	Remainder 10/31/2005	
				Committed Unbilled	Completed Cost Savings
International Epidemiology Inst. Utrecht University	8/31/2005	\$65,340	\$53,757	\$11,583	
Devtrack Pty. Ltd. International Epidemiology Study	8/31/2005	63,500		63,500	
	8/31/2005	37,500		37,500	
Penn State University Database of Mfg. Records	9/30/2005	103,159	95,889	7,270	
International Epidemiology Inst. Patient Quality of Life Survey	3/31/2005	26,362	26,362		
Utrecht University Dutch Follow Up Study	12/22/2005	104,954	75,542	29,412	
Information Systems Laboratories, Noninvasive Assessment of Heart Valves	2/25/2005	77,997	77,997		
BioQuantetics Ultrasound Burst-Spectrography	2/28/2005	139,104	139,104		
Miromico, Inc. Telemonitoring System	4/7/2005	199,400	199,400		
UMC Utrecht Electromagnetic Dip Meter	4/14/2005	37,947	37,947		
Michigan State University Catheter Based and EMAT Detection of SLS	6/30/2005	238,722	227,016		\$11,706
Michigan State University EMAT Continuation Project	5/12/2005	157,111	90,717	66,394	
Eindhoven University Catheter Based Antenna	4/18/2004	106,800		106,800	
Cleveland Clinic 3-D Motion of Heart Valves	3/22/2005	73,134	69,234	3,900	
ACES Evaluation of the Role of Crack Growth and Initiation	11/30/2004	2,100	2,100		

ACES BSCC Valve Performance Modeling Using Element Free Techniques	2/28/2005	17,290	17,290	
ACES Modeling of BSCC Heart Valves, Effect of Compliant Support Conditions	2/28/2005	45,200	45,200	
ACES Relationship of Engineering and Epidemiology	9/30/2005	132,050	120,650	11,400
ACES Hook to Well Separation	9/30/2005	127,675	121,725	5,950
ACES Passive Accoustic Detection	8/31/2005	137,470	137,470	
UAB Evaluate Approach to Improve Risk of Re-Operation	7/18/2004	128,683	112,181	16,502
<b>TOTAL</b>		<b>\$2,021,498</b>	<b>\$1,649,581</b>	<b>\$343,709</b>
				<b>\$28,208</b>

Note - The 1/31/2005 balances are the amounts included in Schedule II of the Supervisory Panel's continuing operation plan.

**Trustees for the Bowling-Pfizer Heart Valve Settlement Funds  
Supervisory Panel Research Projects Initiated After January 31, 2005**

Continuing Operation Plan Future Projects	Termination Date	Contract Amounts			Billed Through 10/31/2005	Remainder 10/31/2005	
		Projected	Actual	Savings		Committed Unbilled	Completed Cost Savings
<b>Committed</b>							
Michigan State University EMAT System	11/12/2006	\$1,000,000	\$982,686	\$17,314		\$982,686	
Sheep Study	6/30/2005	40,000	35,125	4,875	\$34,547		\$578
BioQuantetics Ultrasound Burst-Spect.	12/31/2005	600,000	589,928	10,072	359,834	230,094	
April Interim Funding	4/30/2005		25,535	(25,535)	24,918		617
ACES Passive Accoustics	8/31/2005		5,259	(5,259)	110	5,149	
Cleveland Clinic & STS Guidelines Data		20,000	57,900	(37,900)	57,900		
BioSurg		100,000	230,120	(130,120)	6,750	223,370	
Hershey Imaging		7,902	7,902		7,902		
<b>Total</b>		<b>\$1,767,902</b>	<b>\$1,934,455</b>	<b>(\$166,553)</b>	<b>\$491,961</b>	<b>\$1,441,299</b>	<b>\$1,195</b>
<b>Not Yet Committed</b>							
ACES Passive Accoustics		\$500,000					
Michigan State University EMAT System Testing		30,000					
Hershey Imaging		152,098					
Pilot Test		262,250					
Testing Center		1,597,500					
Guidelines Notification		400,000					
<b>Total</b>		<b>\$2,941,848</b>					
<b>Total</b>		<b>\$4,709,750</b>					

**APPENDIX 3A**

# Hit Report for Bowling-Pfizer.com

	April 2005	May 2005	June 2005
Total Visits	894	792	1164
Average Daily Visits	29	25	38
Average Visit Length	8:49	7:40	10:37
Median Visit Length	1:18	1:59	5:05
International Visits	7.35%	7.32%	5.06%
US Visits	86.08%	80.55%	83.33%
Unknown Origin Visits	6.56%	12.12%	11.59%
Unique Visitors	398	361	574
One-Time Visitors	262	268	379
Multiple-Time Visitors	136	93	195
Top Downloads	Twenty First Report - 32 times	Amended 2003 - 67 times	Amended 2003 - 170 times
	Settlement - 25 times	Doctor Letter 2003 - 65 Times	Pamphlet - 166 times
	Pamphlet - 22 times	Twenty First Report - 56 times	Class Letter 2003 - 84 times
	Spanish Guidelines - 18 times	Settlement - 24 times	Haynes - 61 times
	Class Letter 2003 - 17 times	Class Letter 2003 - 24 times	Twenty First Report - 47 times
	French Guidelines - 16 times	Precautions - 15 times	Doctor Letter 2003 - 44 times
	Amended 2003 - 15 times	Pamphlet - 15 times	Precautions - 41 times
Total Downloads	271	377	886
Top Visitors Locations	Redmond, WA	Altadena, CA	Reston, VA
	Altadena, CA	Redmond, WA	Redmond, WA
	Bremerton, WA	Reston, VA	Stamford, CT
	Stamford, CT	San Francisco, CA	West Newton, MA
	East Lansing, MI	Bremerton, WA	Denver, CO
Countries viewing the site	United States	United States	United States
	France	Netherlands	Saudi Arabia
	Canada	Canada	Canada
	United Kingdom	Seychelles	Brazil
	Poland	Japan	Switzerland
	Taiwan	Taiwan	Germany
	Seychelles	Ireland	United Kingdom
	Brazil	United Kingdom	Netherlands

