



FINANCIAL REPORT

REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION, INC.

YEARS ENDED DECEMBER 31, 2015 AND 2014

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**FINANCIAL REPORT
YEARS ENDED DECEMBER 31, 2015 AND 2014**

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INDEPENDENT AUDITORS' REPORT

To the Board of Directors
Reagan-Udall Foundation for the Food and Drug Administration, Inc.
Washington, D.C.

Report on the Financial Statements

We have audited the accompanying financial statements of Reagan-Udall Foundation for the Food and Drug Administration, Inc., which comprise the statements of financial position as of December 31, 2015 and 2014, and the related statements of activities and changes in net assets and cash flows for the years then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditors consider internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Reagan-Udall Foundation for the Food and Drug Administration, Inc. as of December 31, 2015 and 2014, and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Report on Supplementary Information

Our audits were conducted for the purpose of forming an opinion on the financial statements as a whole. The schedules of functional expenses on page 9 are presented for purposes of additional analysis and are not a required part of the financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the financial statements. The information has been subjected to the auditing procedures applied in the audits of the financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the financial statements or to the financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated in all material respects in relation to the financial statements as a whole.

A handwritten signature in black ink that reads "Thompson Greenspan". The signature is written in a cursive, flowing style.

Fairfax, Virginia
November 21, 2016

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**STATEMENTS OF FINANCIAL POSITION
DECEMBER 31, 2015 AND 2014**

	2015	2014
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 1,197,654	\$ 468,775
Grants receivable	13,929	1,679,448
Prepaid expenses	150,120	73,611
	1,361,703	2,221,834
Property and Equipment		
Property and equipment	13,636	9,716
Website	33,786	33,786
Accumulated depreciation	(42,298)	(34,731)
	5,124	8,771
Other Assets		
Security deposits	17,600	17,600
	17,600	17,600
Total Assets	\$ 1,384,427	\$ 2,248,205
LIABILITIES AND NET ASSETS		
Current Liabilities		
Accounts payable	\$ 518,010	\$ 656,153
Grant refund payable	181,866	255,061
Accrued wages	31,618	16,942
	731,494	928,156
Net Assets		
Unrestricted	11,692	-
Temporarily restricted	641,241	1,320,049
	652,933	1,320,049
Total Liabilities and Net Assets	\$ 1,384,427	\$ 2,248,205

The Notes to Financial Statements are an integral part of these statements.

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**STATEMENTS OF ACTIVITIES AND CHANGES IN NET ASSETS
YEARS ENDED DECEMBER 31, 2015 AND 2014**

	2015			2014		
	Unrestricted	Temporarily Restricted	Total	Unrestricted	Temporarily Restricted	Total
Support and Revenue						
Contributions	\$ 56,222	\$ 150,180	\$ 206,402	\$ 21,108	\$ 52,600	\$ 73,708
Grants	759,789	3,078,070	3,837,859	315,526	3,889,419	4,204,945
Net assets released from restrictions	3,907,058	(3,907,058)	-	3,573,920	(3,573,920)	-
Total Support and Revenue	<u>4,723,069</u>	<u>(678,808)</u>	<u>4,044,261</u>	<u>3,910,554</u>	<u>368,099</u>	<u>4,278,653</u>
Expenses						
Programs	4,287,841	-	4,287,841	3,573,920	-	3,573,920
Development	15,106	-	15,106	16,058	-	16,058
Management and general	408,430	-	408,430	415,903	-	415,903
Total Expenses	<u>4,711,377</u>	<u>-</u>	<u>4,711,377</u>	<u>4,005,881</u>	<u>-</u>	<u>4,005,881</u>
Change in Net Assets	11,692	(678,808)	(667,116)	(95,327)	368,099	272,772
Net Assets, beginning of year	-	1,320,049	1,320,049	95,327	951,950	1,047,277
Net Assets, end of year	<u>\$ 11,692</u>	<u>\$ 641,241</u>	<u>\$ 652,933</u>	<u>\$ -</u>	<u>\$ 1,320,049</u>	<u>\$ 1,320,049</u>

The Notes to Financial Statements are an integral part of these statements.

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2015 AND 2014**

	<u>2015</u>	<u>2014</u>
Cash Flows from Operating Activities		
Change in net assets	\$ (667,116)	\$ 272,772
Adjustments to reconcile change in net assets to net cash provided (used) by operating activities		
Depreciation and amortization	7,567	15,314
(Increase) Decrease in		
Grants receivable	1,665,519	(772,438)
Prepaid expenses	(76,509)	(19,749)
Increase (Decrease) in		
Accounts payable	(138,143)	237,330
Grant refund payable	(73,195)	255,061
Accrued wages	14,676	4,702
	<u>732,799</u>	<u>(7,008)</u>
Net Cash Provided (Used) by Operating Activities		
Cash Flows from Investing Activities		
Increase in security deposits	-	(1,940)
Payments for the purchase of property	(3,920)	(1,804)
	<u>(3,920)</u>	<u>(3,744)</u>
Net Cash Used by Investing Activities		
Net Increase (Decrease) in Cash and Cash Equivalents	728,879	(10,752)
Cash and Cash Equivalents, beginning of year	<u>468,775</u>	<u>479,527</u>
Cash and Cash Equivalents, end of year	<u>\$ 1,197,654</u>	<u>\$ 468,775</u>

The Notes to Financial Statements are an integral part of these statements.

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2015 AND 2014**

1. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Purpose

Reagan-Udall Foundation for the Food and Drug Administration, Inc. (the Foundation) is a non-profit organization created by Congress in 2007 and incorporated under the laws of the state of Maryland. The Foundation was in organization until 2009. The Foundation's primary purpose is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety pursuant to Section 770 of the Federal Food, Drug, and Cosmetic Act. The Foundation's current projects include the Critical Path to Tuberculosis Drug Regimens Project (CPTR), the Innovation in Medical Evidence Development and Surveillance (IMEDS), the Big Data for Patients (BD4P), the Alzheimer's Association fellowship (AA) and the Health Outcome of Interest in secondary or automated data sources project (HOI). The Foundation is currently located in Washington, D.C.

The activities of the Foundation are financed by grants, contributions, and the Food and Drug Administration (the FDA) funds specifically prescribed under the statute to be appropriated to the FDA and then transferred to the Foundation. The Commissioner of the FDA shall transfer not less than \$500,000 and not more than \$1,250,000 for each fiscal year. Funds received from the FDA are to be utilized for the core operations of the Foundation to include strategic planning.

Basis of Accounting

The financial statements of the Foundation have been prepared on the accrual basis of accounting in accordance with generally accepted accounting principles. Accordingly, revenue is recognized when earned and expenses are recognized when incurred.

Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Support and Revenue

The Foundation reports gifts of cash and other assets as restricted support if they are received with donor stipulations that limit the use of the donated assets.

Grants receivable represents amounts which have been promised but not yet received. All grants receivable are expected to be collectable. Various grants received by the Foundation periodically require progress reports on the activities of the Foundation.

Cash and Cash Equivalents

For the purposes of the statements of cash flows, cash equivalents include demand deposits and certificates of deposit with original maturities of three months or less.

The Foundation maintains its cash accounts with one financial institution which, at times, may exceed Federally insured limits of \$250,000. The Foundation has not experienced any losses from such accounts.

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2015 AND 2014**

1. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(continued)

Property and Equipment

The Foundation has a capitalization policy for qualifying assets in excess of \$1,000. Computer equipment and website charges are reported at cost. Assets are depreciated over a three-year estimated life using the straight-line method. Depreciation and amortization expense for the years ended December 31, 2015 and 2014 was \$7,567 and \$15,314, respectively.

Net Assets

Unrestricted net assets are those that are not subject to donor-imposed stipulations. Amounts received that are designated for future periods or restricted by the donor for specific purposes are reported as temporarily restricted or permanently restricted support that increases those net asset classes. When a restriction expires, that is, when a stipulated time or purpose restriction is accomplished, temporarily restricted net assets are reclassified to unrestricted net assets and reported in the statements of activities and changes in net assets as net assets released from restrictions.

Functional Allocation of Expenses

The costs of providing various programs and other activities have been summarized on a functional basis in the statements of activities and changes in net assets. Accordingly, certain costs have been allocated among the programs and supporting services benefited.

Income Tax Status

Under Section 501(c)(3) of the Internal Revenue Code and the applicable income tax regulations of the state of Maryland, the Foundation is exempt from taxes on income related to its exempt purpose.

The Foundation has no uncertain tax positions that qualify for either recognition or disclosure in the financial statements and no interest and penalties have been recorded in the accompanying financial statements related to uncertain tax positions.

The Foundation files Form 990, Return of Organization Exempt from Income Tax, with the Internal Revenue Service. The Foundation is not currently under audit by any income tax jurisdiction.

Donated Services and In-Kind Support

Donated services and in-kind support are recognized as contributions if the services create or enhance nonfinancial assets, require specialized skills performed by people with those skills, or would otherwise be purchased by the Foundation. Donated services of \$195,180 and \$52,600 were recorded for the years ended December 31, 2015 and 2014, respectively, for program and administrative professional services.

Subsequent Events

The date to which events occurring after December 31, 2015, the date of the most recent statement of financial position, have been evaluated for possible adjustment to the financial statements or disclosure is November 21, 2016, which is the date on which the financial statements were available to be issued.

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2015 AND 2014**

2. GRANT REFUND PAYABLE

Subsequent to December 31, 2015, the Foundation returned \$181,866 of unexpensed grant funds to the original donor. The original grant funds were received and recorded as temporarily restricted revenue in 2013. Subsequent to December 31, 2014, the Foundation returned \$255,061 of unexpensed grant funds to the original donor. The original grant funds were received and recorded as temporarily restricted revenue in 2011, with the grand period ending during 2014.

3. TEMPORARILY RESTRICTED NET ASSETS

Temporarily restricted net assets released from restrictions and the remaining temporarily restricted net assets are as follows at December 31:

	2015		2014	
	Released from Restrictions	Temporarily Restricted Net Assets	Released from Restrictions	Temporarily Restricted Net Assets
CPTR	\$ 121,405	\$ 638,040	\$ 195,622	\$ 759,445
IMEDS	3,754,865	3,201	3,107,939	186,939
BD4P	30,788	-	-	-
AA	-	-	33,285	373,665
HOI	-	-	52,600	-
FDA	-	-	184,474	-
Totals	<u>\$ 3,907,058</u>	<u>\$ 641,241</u>	<u>\$ 3,573,920</u>	<u>\$ 1,320,049</u>

4. CONCENTRATION OF RISK

At December 31, 2015 and 2014, six entities accounted for 94 percent of revenue, and seven entities accounted for 96 percent of revenue, respectively. At December 31, 2015 and 2014, one and four entities accounted for all of the grants receivable, respectively.

5. LEASE COMMITMENTS

In October 2011, the Foundation entered into a lease for office space in Washington, D.C., which commenced in November 2011. The Foundation entered into leases for additional office space within the same building during 2013. All the leases automatically renew every 6 months if termination notice is not given to the landlord within 60 days of expiration. The leases are currently scheduled to expire on December 15, 2016. These leases include various services such as furniture rental. Future minimum lease payments under these noncancelable operating leases at December 31, 2015 is \$164,400.

Rent expense for the years ended December 31, 2015 and 2014 was \$177,528 and \$171,314, respectively.

6. RETIREMENT PLAN

The Organization adopted a 401(k) Profit Sharing Plan effective January 1, 2015, in which all employees aged 21 or older and with one year of service are eligible to participate. The Organization made a safe harbor nonelective contribution and a matching contribution for the year ended December 31, 2015. Contributions to the Plan for the year ended December 31, 2015 are \$32,181.

**REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION, INC.**

**SCHEDULES OF FUNCTIONAL EXPENSES
YEARS ENDED DECEMBER 31, 2015 AND 2014**

	2015				2014			
	Programs	Development	Management and General	Total	Programs	Development	Management and General	Total
Salaries and fringe benefits	\$ 739,564	\$ 2,700	\$ 64,959	\$ 807,223	\$ 556,441	\$ 9,344	\$ 149,237	\$ 715,022
Travel, meetings and conferences	89,479	327	7,860	97,666	101,637	4,236	8,793	114,666
Occupancy	169,580	619	14,895	185,094	144,886	2,433	38,858	186,177
Office and communication expenses	59,265	216	5,205	64,686	646,658	45	31,041	677,744
Professional services	3,229,953	11,244	315,511	3,556,708	2,124,298	-	187,974	2,312,272
Totals	\$ 4,287,841	\$ 15,106	\$ 408,430	\$ 4,711,377	\$ 3,573,920	\$ 16,058	\$ 415,903	\$ 4,005,881