

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Financial Statements
and Independent Auditors' Report

December 31, 2016 and 2015

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Financial Statements
December 31, 2016 and 2015

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INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying financial statements of Reagan-Udall Foundation for the Food and Drug Administration, Inc. ("the Foundation"), which comprise the statement of financial position as of December 31, 2016, the related statements of activities and cash flows for the year 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 controls relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit 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 auditor's 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 auditor considers 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.

Auditor's Responsibility (continued)

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 the Foundation as of December 31, 2016, and the changes in its net assets and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

Other Matter

The financial statements of the Foundation as of December 31, 2015, were audited by other auditors whose report, dated November 21, 2016, expressed an unmodified opinion on those statements.

Supplementary and Other Information

Our audit was conducted for the purpose of forming an opinion on the financial statements as a whole. The supplementary information for the year ended December 31, 2016 included on page 14 is presented for purposes of additional analysis and is not a required part of the financial statements. The information for the year ended December 31, 2015 on page 15 was subjected to the auditing procedures applied in the audit of the basic financial statements by other independent auditors, whose report, dated November 21, 2016, indicated that such information is fairly stated in all material respects to the basic statements as a whole. 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 audit 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.



Vienna, Virginia
September 28, 2017

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Statements of Financial Position
December 31, 2016 and 2015

	<u>2016</u>	<u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,513,095	\$ 1,172,430
Certificate of deposit	25,235	25,224
Grants receivable	173,113	13,929
Prepaid expenses and other assets	<u>13,047</u>	<u>150,120</u>
Total current assets:	1,724,490	1,361,703
Deposits	27,732	17,600
Property and equipment, net	<u>55,087</u>	<u>5,124</u>
Total assets	<u><u>\$ 1,807,309</u></u>	<u><u>\$ 1,384,427</u></u>
Liabilities and Net Assets		
Liabilities		
Accounts payable	\$ 69,939	\$ 549,628
Grant refunds payable	-	181,866
Deferred rent and tenant improvement allowance	<u>20,296</u>	<u>-</u>
Total liabilities	<u>90,235</u>	<u>731,494</u>
Net Assets		
Unrestricted	603,142	11,692
Temporarily restricted	<u>1,113,932</u>	<u>641,241</u>
Total net assets	<u>1,717,074</u>	<u>652,933</u>
Total liabilities and net assets	<u><u>\$ 1,807,309</u></u>	<u><u>\$ 1,384,427</u></u>

See accompanying notes.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Statement of Activities
For the Year Ended December 31, 2016

	<u>Unrestricted</u>	<u>Temporarily Restricted</u>	<u>Total</u>
Revenue and Support			
FDA transfer	\$ 1,000,000	\$ -	\$ 1,000,000
Grants and contributions	26,100	2,643,496	2,669,596
Interest income	11	-	11
Released from restrictions	<u>2,170,805</u>	<u>(2,170,805)</u>	<u>-</u>
Total revenue and support	<u>3,196,916</u>	<u>472,691</u>	<u>3,669,607</u>
Expenses			
Programs	<u>2,396,740</u>	<u>-</u>	<u>2,396,740</u>
Supporting services:			
Management and general	188,986	-	188,986
Development	<u>19,740</u>	<u>-</u>	<u>19,740</u>
Total supporting services	<u>208,726</u>	<u>-</u>	<u>208,726</u>
Total expenses	<u>2,605,466</u>	<u>-</u>	<u>2,605,466</u>
Change in Net Assets	591,450	472,691	1,064,141
Net Assets, beginning of year	<u>11,692</u>	<u>641,241</u>	<u>652,933</u>
Net Assets, end of year	<u><u>\$ 603,142</u></u>	<u><u>\$ 1,113,932</u></u>	<u><u>\$ 1,717,074</u></u>

See accompanying notes.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Statement of Activities
For the Year Ended December 31, 2015

	<u>Unrestricted</u>	<u>Temporarily Restricted</u>	<u>Total</u>
Revenue and Support			
FDA transfer	\$ 775,000	\$ -	\$ 775,000
Grants and contributions	620,709	2,453,250	3,073,959
In-kind contributions	195,180	-	195,180
Interest income	11	-	11
Other income	111	-	111
Released from restrictions	<u>3,132,058</u>	<u>(3,132,058)</u>	<u>-</u>
 Total revenue and support	 <u>4,723,069</u>	 <u>(678,808)</u>	 <u>4,044,261</u>
Expenses			
Programs	<u>4,287,841</u>	<u>-</u>	<u>4,287,841</u>
Supporting services:			
Management and general	408,430	-	408,430
Development	<u>15,106</u>	<u>-</u>	<u>15,106</u>
 Total supporting services	 <u>423,536</u>	 <u>-</u>	 <u>423,536</u>
 Total expenses	 <u>4,711,377</u>	 <u>-</u>	 <u>4,711,377</u>
 Change in Net Assets	 11,692	 (678,808)	 (667,116)
 Net Assets, beginning of year	 <u>-</u>	 <u>1,320,049</u>	 <u>1,320,049</u>
 Net Assets, end of year	 <u>\$ 11,692</u>	 <u>\$ 641,241</u>	 <u>\$ 652,933</u>

See accompanying notes.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Statements of Cash Flows
For the Years Ended December 31, 2016 and 2015

	<u>2016</u>	<u>2015</u>
Cash Flows from Operating Activities		
Change in net assets	\$ 1,064,141	\$ (667,116)
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation and amortization	2,953	7,567
Change in operating assets and liabilities:		
(Increase) decrease in:		
Grants receivable	(159,184)	1,665,519
Prepaid expenses and other assets	137,073	(76,509)
Deposits	(10,132)	-
Increase (decrease) in:		
Accounts payable	(479,689)	(123,467)
Grant refunds payable	(181,866)	(73,195)
Deferred rent and tenant improvement allowance	20,296	-
	<u>393,592</u>	<u>732,799</u>
Cash Flows from Investing Activities		
Purchases of property and equipment	(52,916)	(3,920)
Maturity of certificate of deposit	(11)	-
	<u>(52,927)</u>	<u>(3,920)</u>
Net Increase in Cash and Cash Equivalents	340,665	728,879
Cash and Cash Equivalents, beginning of year	<u>1,172,430</u>	<u>443,551</u>
Cash and Cash Equivalents, end of year	<u>\$ 1,513,095</u>	<u>\$ 1,172,430</u>

See accompanying notes.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Notes to Financial Statements
December 31, 2016 and 2015

1. Nature of Operations

Reagan-Udall Foundation for the Food and Drug Administration, Inc. (“the Foundation”) is an independent 501(c)(3) nonprofit organization created by Congress for the purpose of advancing the mission of the Food and Drug Administration (“the FDA”) to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

2. Summary of Significant Accounting Policies

Basis of Accounting and Presentation

The Foundation’s financial statements are prepared on the accrual basis of accounting. Net assets are reported based on the presence or absence of donor-imposed restrictions.

Classification of Net Assets

- *Unrestricted net assets* represent funds that are not subject to donor-imposed stipulations and are available for support of the Foundation’s operations.
- *Temporarily restricted net assets* represent funds subject to donor-imposed restrictions that are met either by actions of the Foundation or by the passage of time.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash Equivalents

For the purpose of the statements of cash flows, the Foundation considers as cash equivalents all highly liquid investments, which can be converted into known amounts of cash and have a maturity period of ninety days or less at the time of purchase.

Certificate of Deposit

At December 31, 2016 and 2015, the Foundation held a certificate of deposit with original maturity dates greater than a period of ninety days that are carried at amortized cost.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Notes to Financial Statements
December 31, 2016 and 2015

2. Summary of Significant Accounting Policies (continued)

Certificate of Deposit (continued)

Interest earned on the certificate of deposit is included in the accompanying statements of activities. The certificate of deposit does not qualify as a security as defined in Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 320, *Investments – Debt and Equity Securities*. Therefore, this investment is not included in the fair value disclosures required by FASB ASC 820, *Fair Value Measurements and Disclosures*.

Grants Receivable

Grants receivable represent unbilled costs incurred on grants and contracts. All grants receivable are stated at the amount management expects to collect for balances outstanding at year-end. Annually, management determines if an allowance for doubtful accounts is necessary based upon a review of outstanding grants receivable, historical collection information, and existing economic conditions. Accounts deemed uncollectible are charged off based on individual credit evaluation and specific circumstances of the parties involved. There was no allowance for doubtful grants receivable at December 31, 2016 and 2015.

Property and Equipment

Property and equipment acquisitions with a cost greater than \$1,000 and a projected useful life exceeding one year are capitalized and recorded at cost. Computer equipment and website charges are reported at cost. Assets are depreciated over a three-year estimated life using the straight-line method. Upon disposal of depreciable assets, the cost and related accumulated depreciation are eliminated from the accounts and the resulting gain or loss is credited or charged to income. Expenditures for repairs and maintenance are expensed as incurred.

Grant Refunds Payable

At December 31, 2015, grant refunds payable represented unspent funds received from a donor. The original grant funds were received and recorded as temporarily restricted revenue in 2013. During the year ended December 31, 2016, \$181,866 was returned to the donor, and was recorded as grant refunds payable in the accompanying statement of financial position at December 31, 2015. There were no grant refunds payable at December 31, 2016.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Notes to Financial Statements
December 31, 2016 and 2015

2. Summary of Significant Accounting Policies (continued)

Revenue Recognition

Grants and contributions are recorded as revenue when received or promised. The Foundation reports gifts of cash and other assets as temporarily restricted support if they are received or promised with donor stipulations that limit the use of the donated assets to one of the Foundation's programs or to a future year. When a donor restriction expires, that is, when a purpose restriction is accomplished or time restriction has elapsed, temporarily restricted net assets are reclassified to unrestricted net assets and reported in the statements of activities as net assets released from restrictions. Temporarily restricted net assets are reported as unrestricted net assets if the restrictions are met in the same period received.

Revenue from all other sources is recognized when earned.

Donated Services

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 \$0 and \$195,180 were recorded for the years ended December 31, 2016 and 2015, respectively, for program and administrative professional services.

Functional Allocation of Expenses

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

Subsequent Events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through September 28, 2017, the date the financial statements were available to be issued.

Subsequent to year-end on January 26, 2017, a grant from the Bill and Melinda Gates Foundation (BMGF) was terminated due to changing priorities at BMGF, and unspent funds of \$571,702 were returned to BMGF. These funds were initially recorded as temporarily restricted revenue in November 2014, when the Foundation was awarded a project support grant from BMGF totaling \$1,229,613 to assist the Foundation's Critical Path to Tuberculosis Drug Regimens (CPTR) project.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Notes to Financial Statements
December 31, 2016 and 2015

2. Summary of Significant Accounting Policies (continued)

Reclassifications

Certain amounts in the 2015 financial statements have been reclassified to conform to the 2016 presentation. These reclassifications have no effect on the change in net assets previously reported.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) 2016-02, *Leases*. The update requires a lessee to recognize a right-of-use asset and lease liability, initially measured at the present value of the lease payments, in its statements of financial position. The guidance also expands the required quantitative and qualitative lease disclosures. The guidance is effective beginning in 2020.

In August 2016, the FASB issued ASU 2016-14, *Presentation of Financial Statements for Not-for-Profit Entities*. The update changes the manner by which nonprofit organizations classify net assets as well as improves information presented in financial statements and notes about nonprofit organization liquidity, financial performance, and cash flows. The guidance is effective beginning in 2018.

3. Concentrations of Risk

Credit Risk

Financial instruments that potentially subject the Foundation to significant concentrations of credit risk consist of cash and cash equivalents, and a certificate of deposit. The Foundation maintains cash deposit and transaction accounts, along with investments, with various financial institutions and these values, from time to time, exceed insurable limits under the Federal Depository Insurance Corporation (FDIC) and Securities Investor Protection Corporation (SIPC). The Foundation has not experienced any credit losses on its cash and cash equivalents, and its certificate of deposit to date as it relates to FDIC and SIPC insurance limits. Management periodically assesses the financial condition of these financial institutions and believes that the risk of any credit loss is minimal.

Revenue Risk

At December 31, 2016 and 2015, six entities accounted for 89% of revenue, and six entities accounted for 94% of revenue, respectively.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Notes to Financial Statements
December 31, 2016 and 2015

4. Property and Equipment

Property and equipment consists of the following at December 31:

	<u>2016</u>	<u>2015</u>
Furniture and fixtures	\$ 51,416	\$ -
Website	33,786	33,786
Computer equipment and software	<u>15,136</u>	<u>13,636</u>
Total property and equipment	100,338	47,422
Less: accumulated depreciation and amortization	<u>(45,251)</u>	<u>(42,298)</u>
Property and equipment, net	<u><u>\$ 55,087</u></u>	<u><u>\$ 5,124</u></u>

5. Temporarily Restricted Net Assets

Temporarily restricted net assets were restricted for the following purposes at December 31:

	<u>2016</u>	<u>2015</u>
Critical Path to Tuberculosis Drug Regiments	\$ 587,516	\$ 638,040
Innovation in Medical Evidence Development and Surveillance	311,483	3,201
Expanded Access	197,945	-
Big Data for Patients	<u>16,988</u>	<u>-</u>
Total temporarily restricted net assets	<u><u>\$ 1,113,932</u></u>	<u><u>\$ 641,241</u></u>

The *Critical Path to Tuberculosis Drug Regiments* was a project to provide leadership and program management support for the CPTR Stakeholder & Community Engagement Workshop and the Global Regulatory Pathway Workgroup. This program was closed in January 2017, and unspent funds were returned to the grantor, as described in Note 2, *Subsequent Events*.

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Notes to Financial Statements
December 31, 2016 and 2015

5. Temporarily Restricted Net Assets (continued)

The *Innovation in Medical Evidence Development and Surveillance (IMEDS)* program facilitates engagement with industry and other researchers to utilize the same tools and methods developed for the FDA's Sentinel System. IMEDS provides the opportunity to leverage expertise and standardized processes for the rapid and robust analysis of regulated products in a post-market setting.

The *Expanded Access (EA)* program provides guidance to physicians, patients, and caregivers through its online EA Navigator. EA, also known as compassionate use, provides some patients who have serious or life-threatening diseases or conditions with access to investigational treatment not approved by the FDA.

The *Big Data for Patients (BD4P)* program aims to increase patients' and advocates' understanding of what big data is, how it can be used, and what the impact is on patient health outcomes. This program will help to make data science more relatable and less intimidating for patients so they are equipped to become true partners in big data initiatives.

6. Commitments and Contingencies

Operating Lease

During 2016, the Foundation's old office space lease expired and the Foundation entered into a new, long-term lease at a new location in Washington, D.C. The new lease commenced on December 31, 2016 and is scheduled to expire on June 15, 2022. The lease includes an annual escalation clause, as well as various lease incentives, which are recognized on a straight-line basis in the accompanying financial statements. Deferred rent represents the unamortized portion of the tenant improvement allowance, and the cumulative difference between the actual rent paid and the straight-line rent.

Future minimum lease payments under the operating lease are as follows at December 31:

2017	\$	101,319
2018		104,105
2019		128,362
2020		131,891
2021		135,518
Thereafter		<u>69,623</u>
Total future minimum lease payments	\$	<u><u>670,818</u></u>

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Notes to Financial Statements
December 31, 2016 and 2015

6. Commitments and Contingencies (continued)

Operating Lease (continued)

Rent expense for the years ended December 31, 2016 and 2015 was \$166,773 and \$177,528, respectively.

Employment Contract

The Foundation has a signed employment agreement with the Executive Director, which contains terms that require severance payments upon the occurrence of certain contractual events.

7. Pension Plan

The Foundation 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 Foundation made a safe harbor non-elective contribution and a matching contribution for the years ended December 31, 2016 and 2015. Contributions to the Plan for the years ended December 31, 2016 and 2015 totaled \$22,980 and \$32,181, respectively.

8. Income Taxes

The Foundation is exempt from payment of taxes on income other than net unrelated business income under Section 501(c)(3) of the Internal Revenue Code (IRC). For the years ended December 31, 2016 and 2015, there was no unrelated business income and, accordingly, no federal or state income taxes have been recorded. Contributions to the Foundation are deductible as provided in IRC Section 170(b)(1)(A)(vi). Management has evaluated the Foundation's tax positions and concluded that the Foundation's financial statements do not include any uncertain tax positions.

SUPPLEMENTARY INFORMATION

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Schedule of Functional Expenses
For the Year Ended December 31, 2016

	Programs	Supporting Services		Total Expenses
		Management and General	Development	
Salaries and fringe benefits	\$ 497,088	\$ 125,788	\$ 15,150	\$ 638,026
Travel, meetings, and conferences	77,506	3,244	472	81,222
Occupancy	145,445	20,065	1,263	166,773
Office and communication	61,440	7,035	697	69,172
Professional services	1,455,261	32,854	2,158	1,490,273
Grants	160,000	-	-	160,000
Total Expenses	\$ 2,396,740	\$ 188,986	\$ 19,740	\$ 2,605,466

Reagan-Udall Foundation for the Food and Drug Administration, Inc.

Schedule of Functional Expenses
For the Year Ended December 31, 2015

	Programs	Supporting Services		Total Expenses
		Management and General	Development	
Salaries and fringe benefits	\$ 739,564	\$ 64,959	\$ 2,700	\$ 807,223
Travel, meetings, and conferences	89,479	7,860	327	97,666
Occupancy	169,580	14,895	619	185,094
Office and communication	59,265	5,205	216	64,686
Professional services	3,229,953	315,511	11,244	3,556,708
Total Expenses	\$ 4,287,841	\$ 408,430	\$ 15,106	\$ 4,711,377