

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

Financial Statements
and Independent Auditors' Report

December 31, 2017 and 2016

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

Financial Statements
December 31, 2017 and 2016

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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 statements of financial position as of December 31, 2017 and 2016, the related statements of activities 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 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 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 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.

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, 2017 and 2016, 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.

Supplementary and Other Information

Our audits were conducted for the purpose of forming an opinion on the financial statements as a whole. The supplementary information included on pages 14-15 is presented for purposes of additional analysis and is 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 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
April 11, 2018

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

Statements of Financial Position
December 31, 2017 and 2016

	<u>2017</u>	<u>2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,387,402	\$ 1,513,095
Certificate of deposit	25,248	25,235
Grants and contributions receivable	80,820	173,113
Prepaid expenses and other assets	<u>15,140</u>	<u>13,047</u>
Total current assets	2,508,610	1,724,490
Deposits	27,732	27,732
Property and equipment, net	<u>119,742</u>	<u>55,087</u>
Total assets	<u><u>\$ 2,656,084</u></u>	<u><u>\$ 1,807,309</u></u>
Liabilities and Net Assets		
Liabilities		
Accounts payable	\$ 380,891	\$ 69,939
Deferred rent and tenant improvement allowance	<u>37,227</u>	<u>20,296</u>
Total liabilities	<u>418,118</u>	<u>90,235</u>
Net Assets		
Unrestricted	1,693,342	603,142
Temporarily restricted	<u>544,624</u>	<u>1,113,932</u>
Total net assets	<u>2,237,966</u>	<u>1,717,074</u>
Total liabilities and net assets	<u><u>\$ 2,656,084</u></u>	<u><u>\$ 1,807,309</u></u>

See accompanying notes.

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

Statement of Activities
For the Year Ended December 31, 2017

	<u>Unrestricted</u>	<u>Temporarily Restricted</u>	<u>Total</u>
Revenue and Support			
FDA transfer	\$ 1,250,000	\$ -	\$ 1,250,000
Grants and contributions	31,048	961,558	992,606
Gala income	90,400	-	90,400
Interest income	13	-	13
Other income	5,818	-	5,818
Released from restrictions	<u>1,530,866</u>	<u>(1,530,866)</u>	<u>-</u>
Total revenue and support	<u>2,908,145</u>	<u>(569,308)</u>	<u>2,338,837</u>
Expenses			
Programs	<u>1,475,346</u>	<u>-</u>	<u>1,475,346</u>
Supporting services:			
Management and general	60,521	-	60,521
Development	<u>282,078</u>	<u>-</u>	<u>282,078</u>
Total supporting services	<u>342,599</u>	<u>-</u>	<u>342,599</u>
Total expenses	<u>1,817,945</u>	<u>-</u>	<u>1,817,945</u>
Change in Net Assets	1,090,200	(569,308)	520,892
Net Assets, beginning of year	<u>603,142</u>	<u>1,113,932</u>	<u>1,717,074</u>
Net Assets, end of year	<u><u>\$ 1,693,342</u></u>	<u><u>\$ 544,624</u></u>	<u><u>\$ 2,237,966</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>

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

Statements of Cash Flows
For the Years Ended December 31, 2017 and 2016

	<u>2017</u>	<u>2016</u>
Cash Flows from Operating Activities		
Change in net assets	\$ 520,892	\$ 1,064,141
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation and amortization	17,366	2,953
Change in operating assets and liabilities:		
(Increase) decrease in:		
Grants and contributions receivable	92,293	(159,184)
Prepaid expenses and other assets	(2,093)	137,073
Deposits	-	(10,132)
Increase (decrease) in:		
Accounts payable	310,952	(479,689)
Grant refunds payable	-	(181,866)
Deferred rent and tenant improvement allowance	16,931	20,296
	<u>956,341</u>	<u>393,592</u>
Cash Flows from Investing Activities		
Purchases of property and equipment	(82,021)	(52,916)
Maturity of certificate of deposit	(13)	(11)
	<u>(82,034)</u>	<u>(52,927)</u>
Net Increase in Cash and Cash Equivalents	874,307	340,665
Cash and Cash Equivalents, beginning of year	<u>1,513,095</u>	<u>1,172,430</u>
Cash and Cash Equivalents, end of year	<u><u>\$ 2,387,402</u></u>	<u><u>\$ 1,513,095</u></u>

See accompanying notes.

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

Notes to Financial Statements
December 31, 2017 and 2016

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.

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, 2017 and 2016, the Foundation held a certificate of deposit with original maturity dates greater than a period of ninety days that are carried at amortized cost. 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*.

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

Notes to Financial Statements
December 31, 2017 and 2016

2. Summary of Significant Accounting Policies (continued)

Grants and Contributions Receivable

Grants receivable represent contributions and unbilled costs incurred on grants and contracts. All grants and contributions 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 and contributions receivable at December 31, 2017 and 2016.

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.

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.

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

Notes to Financial Statements
December 31, 2017 and 2016

2. Summary of Significant Accounting Policies (continued)

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.

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 April 11, 2018, the date the financial statements were available to be issued.

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.

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

Notes to Financial Statements
December 31, 2017 and 2016

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 with various financial institutions and these values, from time to time, exceed insurable limits under the Federal Deposit Insurance Corporation (FDIC). 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 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, 2017 and 2016, four entities accounted for 99% of revenue and six entities accounted for 89% of revenue, respectively.

4. Property and Equipment

Property and equipment consists of the following at December 31:

	<u>2017</u>	<u>2016</u>
Furniture and fixtures	\$ 51,416	\$ 51,416
Website	114,359	33,786
Computer equipment and software	<u>16,584</u>	<u>15,136</u>
Total property and equipment	182,359	100,338
Less: accumulated depreciation and amortization	<u>(62,617)</u>	<u>(45,251)</u>
Property and equipment, net	<u><u>\$ 119,742</u></u>	<u><u>\$ 55,087</u></u>

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

Notes to Financial Statements
December 31, 2017 and 2016

5. Temporarily Restricted Net Assets

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

	<u>2017</u>	<u>2016</u>
Innovation in Medical Evidence Development and Surveillance	\$ 321,279	\$ 311,483
Expanded Access	211,991	197,945
Big Data for Patients	11,354	16,988
Critical Path to Tuberculosis Drug Regiments	<u>-</u>	<u>587,516</u>
Total temporarily restricted net assets	<u>\$ 544,624</u>	<u>\$ 1,113,932</u>

The *Critical Path to Tuberculosis Drug Regiments* (CPTR) 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.

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.

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

Notes to Financial Statements
December 31, 2017 and 2016

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:

2018	\$	104,105
2019		128,362
2020		131,891
2021		135,518
2022		69,623
		<hr/>
Total future minimum lease payments	\$	<u>569,499</u>

Occupancy expense for the years ended December 31, 2017 and 2016 was \$122,831 and \$166,773, 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, 2017 and 2016. Contributions to the plan for the years ended December 31, 2017 and 2016 totaled \$15,467 and \$22,980, respectively.

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

Notes to Financial Statements
December 31, 2017 and 2016

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, 2017 and 2016, 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, 2017

	Programs	Supporting Services		Total Expenses
		Management and General	Development	
Salaries and fringe benefits	\$ 542,340	\$ 51,737	\$ 188,369	\$ 782,446
Travel, meetings, and conferences	46,972	355	30,129	77,456
Occupancy	105,455	2,869	14,507	122,831
Office and communication	193,085	1,956	10,470	205,511
Professional services	587,494	3,604	38,603	629,701
Total Expenses	\$ 1,475,346	\$ 60,521	\$ 282,078	\$ 1,817,945

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