

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

Financial Statements  
and Independent Auditors' Report

December 31, 2018 and 2017

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

Financial Statements  
December 31, 2018 and 2017

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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, 2018 and 2017; the related statements of activities, functional expenses, 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.

*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, 2018 and 2017, 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.

Handwritten signature in black ink that reads "Rogers + Company PLLC". The signature is written in a cursive, slightly stylized font.

Vienna, Virginia  
May 9, 2019

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

### Statements of Financial Position December 31, 2018 and 2017

	2018	2017
<b>Assets</b>		
Current assets:		
Cash	\$ 1,622,387	\$ 2,387,402
Certificates of deposit	1,379,400	25,248
Grants and contributions receivable	36,305	80,820
Accrued interest receivable	5,019	-
Prepaid expenses and other assets	19,499	15,140
	<hr/>	<hr/>
Total current assets	3,062,610	2,508,610
Deposits	14,032	27,732
Property and equipment, net	87,656	119,742
	<hr/>	<hr/>
Total assets	\$ 3,164,298	\$ 2,656,084
	<hr/> <hr/>	<hr/> <hr/>
<b>Liabilities and Net Assets</b>		
<b>Liabilities</b>		
Accounts payable and accrued expenses	\$ 175,089	\$ 380,891
Deferred revenue	106,875	-
Deferred rent and tenant improvement allowance	51,405	37,227
	<hr/>	<hr/>
Total liabilities	333,369	418,118
	<hr/>	<hr/>
<b>Net Assets</b>		
Without donor restrictions	2,253,793	1,693,342
With donor restrictions	577,136	544,624
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Total net assets	2,830,929	2,237,966
	<hr/>	<hr/>
Total liabilities and net assets	\$ 3,164,298	\$ 2,656,084
	<hr/> <hr/>	<hr/> <hr/>

See accompanying notes.

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

Statement of Activities  
For the Year Ended December 31, 2018

	<u>Without Donor Restrictions</u>	<u>With Donor Restrictions</u>	<u>Total</u>
<b>Revenue and Support</b>			
FDA transfer	\$ 1,250,000	\$ -	\$ 1,250,000
Contracts	573,125	-	573,125
Grants and contributions	60,082	414,638	474,720
Sponsorships	123,174	-	123,174
Gala income, net of direct benefits to donors of \$47,817	2,433	-	2,433
In-kind contributions	8,000	-	8,000
Interest income	9,172	-	9,172
Released from restrictions	382,126	(382,126)	-
	<u>2,408,112</u>	<u>32,512</u>	<u>2,440,624</u>
<b>Expenses</b>			
Programs	<u>1,580,041</u>	<u>-</u>	<u>1,580,041</u>
Supporting services:			
Management and general	145,059	-	145,059
Development	<u>122,561</u>	<u>-</u>	<u>122,561</u>
Total supporting services	<u>267,620</u>	<u>-</u>	<u>267,620</u>
Total expenses	<u>1,847,661</u>	<u>-</u>	<u>1,847,661</u>
<b>Change in Net Assets</b>	560,451	32,512	592,963
<b>Net Assets</b> , beginning of year	<u>1,693,342</u>	<u>544,624</u>	<u>2,237,966</u>
<b>Net Assets</b> , end of year	<u>\$ 2,253,793</u>	<u>\$ 577,136</u>	<u>\$ 2,830,929</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>Without Donor Restrictions</u>	<u>With Donor Restrictions</u>	<u>Total</u>
<b>Revenue and Support</b>			
FDA transfer	\$ 1,250,000	\$ -	\$ 1,250,000
Grants and contributions	31,048	961,558	992,606
Sponsorships	57,400	-	57,400
Gala income, net of direct benefits to donors of \$27,523	5,477	-	5,477
Other income	5,818	-	5,818
Interest income	13	-	13
Released from restrictions	<u>1,530,866</u>	<u>(1,530,866)</u>	<u>-</u>
Total revenue and support	<u>2,880,622</u>	<u>(569,308)</u>	<u>2,311,314</u>
<b>Expenses</b>			
Programs	<u>1,475,346</u>	<u>-</u>	<u>1,475,346</u>
Supporting services:			
Management and general	60,521	-	60,521
Development	<u>254,555</u>	<u>-</u>	<u>254,555</u>
Total supporting services	<u>315,076</u>	<u>-</u>	<u>315,076</u>
Total expenses	<u>1,790,422</u>	<u>-</u>	<u>1,790,422</u>
<b>Change in Net Assets</b>	1,090,200	(569,308)	520,892
<b>Net Assets, beginning of year</b>	<u>603,142</u>	<u>1,113,932</u>	<u>1,717,074</u>
<b>Net Assets, end of year</b>	<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 Functional Expenses  
For the Year Ended December 31, 2018

	Programs	Supporting Services		Total Expenses
		Management and General	Development	
Salaries and fringe benefits	\$ 706,718	\$ 98,078	\$ 77,796	\$ 882,592
Travel, meetings, and conferences	21,687	1,049	795	23,531
Occupancy	100,627	10,760	8,163	119,550
Office and communication	75,727	7,573	6,119	89,419
Professional services	675,282	27,599	29,688	732,569
<b>Total Expenses</b>	<b>\$ 1,580,041</b>	<b>\$ 145,059</b>	<b>\$ 122,561</b>	<b>\$ 1,847,661</b>

*See accompanying notes.*



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

Statement 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	2,606	49,933
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
<b>Total Expenses</b>	<b>\$ 1,475,346</b>	<b>\$ 60,521</b>	<b>\$ 254,555</b>	<b>\$ 1,790,422</b>

*See accompanying notes.*

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

Statements of Cash Flows  
For the Years Ended December 31, 2018 and 2017

	<u>2018</u>	<u>2017</u>
<b>Cash Flows from Operating Activities</b>		
Change in net assets	\$ 592,963	\$ 520,892
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation and amortization	37,140	17,366
Change in operating assets and liabilities:		
Decrease (increase) in:		
Grants and contributions receivable	44,515	92,293
Accrued interest receivable	(5,019)	-
Prepaid expenses and other assets	(4,359)	(2,093)
Deposits	13,700	-
(Decrease) increase in:		
Accounts payable and accrued expenses	(205,802)	310,952
Deferred revenue	106,875	-
Deferred rent and tenant improvement allowance	14,178	16,931
	<u>594,191</u>	<u>956,341</u>
<b>Cash Flows from Investing Activities</b>		
Purchases of property and equipment	(5,054)	(82,021)
Purchases of certificates of deposit	<u>(1,354,152)</u>	<u>(13)</u>
Net cash used in investing activities	<u>(1,359,206)</u>	<u>(82,034)</u>
<b>Net (Decrease) Increase in Cash</b>	(765,015)	874,307
<b>Cash, beginning of year</b>	<u>2,387,402</u>	<u>1,513,095</u>
<b>Cash, end of year</b>	<u>\$ 1,622,387</u>	<u>\$ 2,387,402</u>

*See accompanying notes.*

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

Notes to Financial Statements  
December 31, 2018 and 2017

## 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

- *Net assets without donor restrictions* represent funds that are not subject to donor-imposed stipulations and are available for support of the Foundation’s operations.
- *Net assets with donor restrictions* 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.

### Certificates of Deposit

At December 31, 2018 and 2017, the Foundation held certificates of deposit with original maturity dates greater than a period of ninety days that are carried at amortized cost. Interest earned on the certificates of deposit is included in the accompanying statements of activities. The certificates of deposit do not qualify as a security as defined in Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 320, *Investments – Debt and Equity Securities*. Therefore, these investments are 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, 2018 and 2017

### 2. Summary of Significant Accounting Policies (continued)

#### Grants and Contributions Receivable

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, 2018 and 2017.

#### 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 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, net assets with donor restrictions are reclassified to net assets without donor restrictions and reported in the statements of activities as net assets released from restrictions. Net assets with donor restrictions are reported as net assets without donor restrictions if the restrictions are met in the same period as received.

Contracts are considered exchange transactions and are recognized as revenue when the related expenses are incurred. Cash received in excess of costs incurred is reflected as a component of deferred revenue in the accompanying statements of financial position.

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, 2018 and 2017

### 2. Summary of Significant Accounting Policies (continued)

#### In-Kind Contributions

The Foundation receives in-kind contributions of facilities and use of event space for the gala event. In-kind contributions are recorded in the accompanying statements of activities at their estimated fair value at the date of receipt, totaling \$8,000 for the year ended December 31, 2018. There were no in-kind contributions received during the year ended December 31, 2017.

#### Functional Allocation of Expenses

The costs of program and supporting services activities have been summarized on a functional basis in the statements of activities. The statements of functional expenses present the natural classification detail of expenses by function. Accordingly, certain costs have been allocated among the programs and supporting services benefited.

#### Advertising Costs

The Foundation expenses advertising costs as incurred. Advertising expenses were \$35,124 and \$9,167 for the years ended December 31, 2018 and 2017, respectively.

#### Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (ASU) 2014-09 – *Revenue from Contracts with Customers* (Topic 606). The update establishes a comprehensive revenue recognition standard for virtually all industries including those that previously followed industry-specific guidance. The update requires that revenue be recognized to depict the transfer of promised goods and services to customers in an amount that reflects consideration to which the entity expects to be entitled in exchange for these goods and services. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers* (Topic 606) – *Deferral of the Effective Date*, which deferred the effective date for one year. The guidance is effective beginning in 2019. Management continues to evaluate the potential impact of this update on the Foundation’s financial statements.

In February 2016, the FASB issued 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. Management continues to evaluate the potential impact of this update on the Foundation’s financial statements.

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

Notes to Financial Statements  
December 31, 2018 and 2017

### 2. Summary of Significant Accounting Policies (continued)

#### Recently Issued Accounting Pronouncements (continued)

In August 2018, the FASB issued ASU 2018-08, *Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*. This standard provides clarifications on recognition of contributions and grants (including government grants). This standard is effective for the Foundation beginning in 2019. Management continues to evaluate the potential impact of this update on the Foundation's financial statements.

#### Adopted Accounting Pronouncement

On August 18, 2016, the FASB issued ASU 2016-14, *Not-for-Profit Entities* (Topic 958) – *Presentation of Financial Statements of Not-for-Profit Entities*. The update changed the manner by which nonprofit organization's classify net assets as well as improved information presented in financial statements and notes about nonprofit organization's liquidity, financial performance, and cash flows. The Foundation has implemented ASU 2016-14 and has adjusted the presentation of the financial statements accordingly, except for liquidity and availability, which is permitted by the ASU in the year of adoption. The ASU has been applied retrospectively to all periods presented. The implementation had no impact on previously reported net assets.

#### Subsequent Events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through May 9, 2019, the date the financial statements were available to be issued.

### 3. Liquidity and Availability

The Foundation has \$2,465,975 of financial assets available within one year of the statement of financial position date. The Foundation strives to maintain financial assets on hand to meet 90 days of general expenditures. Management periodically reviews the Foundation's liquid asset needs and adjusts the cash balances as necessary. Amounts in excess of operating liquidity needs are invested in short-term certificates of deposit.

The following table reflects the Foundation's financial assets as of December 31, 2018, reduced by amounts that are not available to meet general expenditures within one year of the statement of financial position date. Amounts not available to meet general expenditures within one year include net assets with donor restrictions.

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

Notes to Financial Statements  
December 31, 2018 and 2017

### 3. Liquidity and Availability (continued)

Financial assets available for general expenditure, that is, without donor or other restrictions limiting their use, within one year of the statement of financial position date, comprise the following:

Cash	\$	1,622,387
Certificates of deposit – appropriated for current use within one year		1,379,400
Grants and contributions receivable		36,305
Accrued interest receivable		5,019
Less: restricted by donors with purpose restrictions		<u>(577,136)</u>
Total available for general expenditures	\$	<u><u>2,465,975</u></u>

### 4. Concentrations of Risk

#### Credit Risk

Financial instruments that potentially subject the Foundation to significant concentrations of credit risk consist of cash and certificates 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 certificates 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

During the years ended December 31, 2018 and 2017, the Foundation received 45% and 53%, respectively, of its total revenue and support from the FDA. Any significant reduction in this funding may adversely impact the Foundation's financial position and its ability to carry out its program activities.

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

Notes to Financial Statements  
December 31, 2018 and 2017

### 5. Property and Equipment

Property and equipment consists of the following at December 31:

	<u>2018</u>	<u>2017</u>
Furniture and fixtures	\$ 51,416	\$ 51,416
Website	117,714	114,359
Computer equipment and software	<u>18,282</u>	<u>16,584</u>
Total property and equipment	187,412	182,359
Less: accumulated depreciation and amortization	<u>(99,756)</u>	<u>(62,617)</u>
Property and equipment, net	<u><u>\$ 87,656</u></u>	<u><u>\$ 119,742</u></u>

### 6. Net Assets with Donor Restrictions

Net assets with donor restrictions were restricted for the following purposes at December 31:

	<u>2018</u>	<u>2017</u>
Innovation in Medical Evidence Development and Surveillance	\$ 387,348	\$ 321,279
Expanded Access	189,788	211,991
Big Data for Patients	<u>-</u>	<u>11,354</u>
Total net assets with donor restrictions	<u><u>\$ 577,136</u></u>	<u><u>\$ 544,624</u></u>

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.



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

Notes to Financial Statements  
December 31, 2018 and 2017

### 6. Net Assets with Donor Restrictions (continued)

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.

### 7. Commitments and Contingencies

#### Operating Lease

During 2016, the Foundation's old office space lease expired and the Foundation entered into a long-term lease at a location in Washington, D.C. The 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:

2019	\$	128,362
2020		131,891
2021		135,518
2022		69,623
		<hr/>
Total future minimum lease payments	\$	465,394
		<hr/> <hr/>

Occupancy expense for the years ended December 31, 2018 and 2017 was \$119,550 and \$122,831, 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.

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

Notes to Financial Statements  
December 31, 2018 and 2017

### **8. 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, 2018 and 2017. Contributions to the plan for the years ended December 31, 2018 and 2017 totaled \$19,840 and \$15,467, respectively.

### **9. Functionalized Expenses**

The financial statements report certain categories of expenses that are attributed to more than one program or supporting function. Therefore, expenses require allocation on a reasonable basis that is consistently applied. All costs incurred directly for a certain program or grant are coded directly or split among those activities. Personnel costs are allocated according to estimates of each individual's time and effort spent in the various functions of the Foundation. Allocated personnel costs include salary expenses, payroll taxes, benefit expenses, retirement plan expenses, and other fringe benefit expenses.

### **10. 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, 2018 and 2017, there was no significant 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.