

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

Financial Statements  
and Independent Auditors' Report

December 31, 2019 and 2018

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

Financial Statements  
December 31, 2019 and 2018

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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, 2019 and 2018; 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.

***Emphasis of Matter***

As discussed in Note 2 to the financial statements, the Foundation adopted Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers* (Topic 606) and FASB ASU 2018-08, *Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*. Our opinion is not modified with respect to this matter.

***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, 2019 and 2018, 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.

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

Vienna, Virginia  
May 28, 2020

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

Statements of Financial Position  
December 31, 2019 and 2018

	<u>2019</u>	<u>2018</u>
<b>Assets</b>		
Current assets:		
Cash	\$ 308,782	\$ 1,622,387
Certificates of deposit	3,381,420	1,379,400
Grants and contributions receivable	194,410	36,305
Accrued interest receivable	13,740	5,019
Prepaid expenses and other assets	<u>32,117</u>	<u>19,499</u>
Total current assets	3,930,469	3,062,610
Deposits	14,032	14,032
Property and equipment, net	<u>120,857</u>	<u>87,656</u>
Total assets	<u>\$ 4,065,358</u>	<u>\$ 3,164,298</u>
<b>Liabilities and Net Assets</b>		
<b>Liabilities</b>		
Accounts payable and accrued expenses	\$ 460,810	\$ 175,089
Deferred revenue	474,070	106,875
Deferred rent and tenant improvement allowance	<u>41,326</u>	<u>51,405</u>
Total liabilities	<u>976,206</u>	<u>333,369</u>
<b>Net Assets</b>		
Without donor restrictions	2,679,562	2,253,793
With donor restrictions	<u>409,590</u>	<u>577,136</u>
Total net assets	<u>3,089,152</u>	<u>2,830,929</u>
Total liabilities and net assets	<u>\$ 4,065,358</u>	<u>\$ 3,164,298</u>

*See accompanying notes.*

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

Statement of Activities  
For the Year Ended December 31, 2019

	<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	920,539	-	920,539
Grants and contributions	12,950	337,500	350,450
Sponsorships	199,694	-	199,694
Gala income, net of direct benefits to donors of \$69,956	22,794	-	22,794
Interest income	35,993	-	35,993
Released from restrictions	<u>505,046</u>	<u>(505,046)</u>	<u>-</u>
Total revenue and support	<u>2,947,016</u>	<u>(167,546)</u>	<u>2,779,470</u>
<b>Expenses</b>			
Programs	<u>2,160,296</u>	<u>-</u>	<u>2,160,296</u>
Supporting services:			
Management and general	208,030	-	208,030
Development	<u>152,921</u>	<u>-</u>	<u>152,921</u>
Total supporting services	<u>360,951</u>	<u>-</u>	<u>360,951</u>
Total expenses	<u>2,521,247</u>	<u>-</u>	<u>2,521,247</u>
<b>Change in Net Assets</b>	425,769	(167,546)	258,223
<b>Net Assets, beginning of year</b>	<u>2,253,793</u>	<u>577,136</u>	<u>2,830,929</u>
<b>Net Assets, end of year</b>	<u><u>\$ 2,679,562</u></u>	<u><u>\$ 409,590</u></u>	<u><u>\$ 3,089,152</u></u>

*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
Other income	8,000	-	8,000
Interest income	9,172	-	9,172
Released from restrictions	382,126	(382,126)	-
	<hr/>	<hr/>	<hr/>
Total revenue and support	2,408,112	32,512	2,440,624
	<hr/>	<hr/>	<hr/>
<b>Expenses</b>			
Programs	1,580,041	-	1,580,041
	<hr/>	<hr/>	<hr/>
Supporting services:			
Management and general	145,059	-	145,059
Development	122,561	-	122,561
	<hr/>	<hr/>	<hr/>
Total supporting services	267,620	-	267,620
	<hr/>	<hr/>	<hr/>
Total expenses	1,847,661	-	1,847,661
	<hr/>	<hr/>	<hr/>
<b>Change in Net Assets</b>	560,451	32,512	592,963
<b>Net Assets, beginning of year</b>	1,693,342	544,624	2,237,966
	<hr/>	<hr/>	<hr/>
<b>Net Assets, end of year</b>	\$ 2,253,793	\$ 577,136	\$ 2,830,929
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*See accompanying notes.*

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

Statement of Functional Expenses  
For the Year Ended December 31, 2019

	Programs	Supporting Services		Total Expenses
		Management and General	Development	
Salaries and fringe benefits	\$ 948,214	\$ 111,371	\$ 109,967	\$ 1,169,552
Professional services	961,071	72,627	23,094	1,056,792
Office and communication	115,074	11,163	8,952	135,189
Occupancy	103,406	10,735	9,099	123,240
Travel, meetings, and conferences	32,531	2,134	1,809	36,474
<b>Total Expenses</b>	<b>\$ 2,160,296</b>	<b>\$ 208,030</b>	<b>\$ 152,921</b>	<b>\$ 2,521,247</b>

*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
Professional services	675,282	27,599	29,688	732,569
Office and communication	75,727	7,573	6,119	89,419
Occupancy	100,627	10,760	8,163	119,550
Travel, meetings, and conferences	21,687	1,049	795	23,531
<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.**

Statements of Cash Flows  
For the Years Ended December 31, 2019 and 2018

	<u>2019</u>	<u>2018</u>
<b>Cash Flows from Operating Activities</b>		
Change in net assets	\$ 258,223	\$ 592,963
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation and amortization	43,137	37,140
Change in operating assets and liabilities:		
Decrease (increase) in:		
Grants and contributions receivable	(158,105)	44,515
Accrued interest receivable	(8,721)	(5,019)
Prepaid expenses and other assets	(12,618)	(4,359)
Deposits	-	13,700
(Decrease) increase in:		
Accounts payable and accrued expenses	285,721	(205,802)
Deferred revenue	367,195	106,875
Deferred rent and tenant improvement allowance	(10,079)	14,178
Net cash provided by operating activities	<u>764,753</u>	<u>594,191</u>
<b>Cash Flows from Investing Activities</b>		
Purchases of property and equipment	(76,338)	(5,054)
Purchases of certificates of deposit	(2,027,273)	(1,354,152)
Redemption on maturities of certificates of deposit	25,253	-
Net cash used in investing activities	<u>(2,078,358)</u>	<u>(1,359,206)</u>
<b>Net Decrease in Cash</b>	(1,313,605)	(765,015)
<b>Cash, beginning of year</b>	<u>1,622,387</u>	<u>2,387,402</u>
<b>Cash, end of year</b>	<u>\$ 308,782</u>	<u>\$ 1,622,387</u>

*See accompanying notes.*

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

Notes to Financial Statements  
December 31, 2019 and 2018

### 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. The central focus of the Foundation is to assist in the creation of new, applied scientific knowledge, tools, standards and approaches the FDA needs to evaluate products more effectively, predictably and efficiently, and thereby enhance the agency’s ability to protect and promote the health of the general public.

### 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.

#### Certificates of Deposit

At December 31, 2019 and 2018, 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, 2019 and 2018

### 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, 2019 and 2018.

#### 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 conditioned upon achieving certain milestones, performance requirements, and the incurrence of qualifying expenses. Contracts liabilities are reported as 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, 2019 and 2018

### 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, 2019.

#### Advertising Costs

Advertising costs are expensed as incurred, and approximated \$25,473 and \$35,124 during the years ended December 31, 2019 and 2018, respectively.

#### 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, 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.

#### 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.

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

Notes to Financial Statements  
December 31, 2019 and 2018

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

#### 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. Management continues to evaluate the potential impact of this update on the Foundation's financial statements.

#### Adopted Accounting Pronouncement

FASB ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606), as amended, supersedes or replaces nearly all revenue recognition guidance under accounting principles generally accepted in the United States of America. These standards establish a new contract and control-based revenue recognition model, change the basis for deciding when revenue is recognized over time or at a point in time, and expand disclosures about revenue. The Foundation has implemented Topic 606 and has adjusted, if applicable, the presentation in these financial statements accordingly. The amendments have been applied retrospectively to all periods presented. The implementation had no impact on the previously reported net assets.

In June 2018, the FASB issued ASU 2018-08, *Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*. This standard assists entities in evaluating whether transactions should be accounted for as contributions or exchange transactions and determining whether a contribution is conditional. We have implemented the provisions of ASU 2018-08 applicable to both contributions received and to contributions made in the accompanying financial statements under a modified prospective basis. Accordingly, there is no effect on net assets in connection with our implementation of ASU 2018-08.

#### Subsequent Events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through May 28, 2020, the date the financial statements were available to be issued.

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

Notes to Financial Statements  
December 31, 2019 and 2018

### 3. 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, 2019 and 2018, the Foundation received 45% and 51%, 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.

### 4. Liquidity and Availability

As part of its liquidity management plan, 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, 2019 and 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, 2019 and 2018

### 4. Liquidity and Availability (continued)

Financial assets available for general expenditures, that is, without donor or other restrictions limiting their use, within one year of the statements of financial position date, comprise the following at December 31:

	<u>2019</u>	<u>2018</u>
Cash	\$ 308,782	\$ 1,622,387
Certificates of deposit	3,381,420	1,379,400
Grants and contributions receivable	194,410	36,305
Accrued interest receivable	13,740	5,019
Less: restricted by donors with purpose restrictions	<u>(409,590)</u>	<u>(577,136)</u>
Total available for general expenditures	<u>\$ 3,488,762</u>	<u>\$ 2,465,975</u>

### 5. Property and Equipment

Property and equipment consists of the following at December 31:

	<u>2019</u>	<u>2018</u>
Furniture and fixtures	\$ 51,416	\$ 51,416
Website	184,651	117,714
Computer equipment and software	<u>27,683</u>	<u>18,282</u>
Total property and equipment	263,750	187,412
Less: accumulated depreciation and amortization	<u>(142,893)</u>	<u>(99,756)</u>
Property and equipment, net	<u>\$ 120,857</u>	<u>\$ 87,656</u>



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

Notes to Financial Statements  
December 31, 2019 and 2018

### 6. Net Assets With Donor Restrictions

Net assets with donor restrictions consist of the following purposes at December 31:

	<u>2019</u>	<u>2018</u>
Innovation in Medical Evidence Development and Surveillance	\$ 275,601	\$ 387,348
Expanded Access	<u>133,989</u>	<u>189,788</u>
Total net assets with donor restrictions	<u>\$ 409,590</u>	<u>\$ 577,136</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.

### 7. Operating Lease

The Foundation is leasing an office space in Washington, D.C., which 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. Occupancy expense for the years ended December 31, 2019 and 2018 was \$123,240 and \$119,550, respectively.

Future minimum lease payments are as follows at December 31:

2020	\$ 131,891
2021	135,518
2022	<u>69,623</u>
Total future minimum lease payments	<u>\$ 337,032</u>

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

Notes to Financial Statements  
December 31, 2019 and 2018

### 8. Revenue from Contracts with Customers

Contracts revenue includes medical research projects with several pharmaceutical companies. The Foundation conducts its work in partnership with selected data partners through access to the IMEDS database. The performance obligations for medical research and access to the IMEDS database are satisfied at the point in time when milestones are reached and expenses are incurred by the data partners.

The following table provides information about changes in deferred revenue for the years ended December 31:

	<u>2019</u>	<u>2018</u>
Deferred revenue, beginning of year	\$ 106,875	\$ -
Increase due to cash received	<u>367,195</u>	<u>106,875</u>
Deferred revenue, end of year	<u><u>\$ 474,070</u></u>	<u><u>\$ 106,875</u></u>

### 9. Pension Plan

The Foundation adopted a 401(k) Profit Sharing Plan effective on January 1, 2015 and amended on January 1, 2019, in which all employees aged 21 or older and with six months 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, 2019 and 2018. Contributions to the plan for the years ended December 31, 2019 and 2018 totaled \$38,532 and \$19,840, respectively.

### 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, 2019 and 2018, 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.