

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

Financial Statements
and Independent Auditors' Report

December 31, 2020 and 2019

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

Financial Statements
December 31, 2020 and 2019

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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, 2020 and 2019; 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, 2020 and 2019, 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
April 28, 2021

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

Statements of Financial Position
December 31, 2020 and 2019

	2020	2019
Assets		
Current assets:		
Cash	\$ 879,236	\$ 308,782
Certificates of deposit	3,026,785	3,381,420
Grants and contributions receivable	545,867	66,676
Contracts receivable	441,971	127,734
Accrued interest receivable	156	13,740
Prepaid expenses and other assets	48,524	32,117
	<hr/>	<hr/>
Total current assets	4,942,539	3,930,469
Deposits	14,032	14,032
Property and equipment, net	85,647	120,857
	<hr/>	<hr/>
Total assets	<u>\$ 5,042,218</u>	<u>\$ 4,065,358</u>
 Liabilities and Net Assets		
Liabilities		
Accounts payable and accrued expenses	\$ 775,660	\$ 71,335
Contracts payable – data partners	620,267	389,475
Deferred contracts revenue	114,329	474,070
Deferred rent and tenant improvement allowance	27,717	41,326
	<hr/>	<hr/>
Total liabilities	1,537,973	976,206
	<hr/>	<hr/>
Net Assets		
Without donor restrictions	3,285,207	2,679,562
With donor restrictions	219,038	409,590
	<hr/>	<hr/>
Total net assets	3,504,245	3,089,152
	<hr/>	<hr/>
Total liabilities and net assets	<u>\$ 5,042,218</u>	<u>\$ 4,065,358</u>

See accompanying notes.

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

Statement of Activities
For the Year Ended December 31, 2020

	<u>Without Donor Restrictions</u>	<u>With Donor Restrictions</u>	<u>Total</u>
Revenue and Support			
FDA transfer	\$ 1,250,000	\$ -	\$ 1,250,000
Contracts	2,485,707	-	2,485,707
Government grant	462,867	-	462,867
Contributions	16,978	275,000	291,978
Sponsorships	387,150	-	387,150
Gala income	20,100	-	20,100
Interest income	21,782	-	21,782
Released from restrictions	465,552	(465,552)	-
	<u>5,110,136</u>	<u>(190,552)</u>	<u>4,919,584</u>
Expenses			
Programs	3,947,866	-	3,947,866
Supporting services:			
Management and general	218,032	-	218,032
Development	276,592	-	276,592
Costs of direct benefits to donors	62,001	-	62,001
	<u>556,625</u>	<u>-</u>	<u>556,625</u>
Total expenses	<u>4,504,491</u>	<u>-</u>	<u>4,504,491</u>
Change in Net Assets	605,645	(190,552)	415,093
Net Assets, beginning of year	<u>2,679,562</u>	<u>409,590</u>	<u>3,089,152</u>
Net Assets, end of year	<u>\$ 3,285,207</u>	<u>\$ 219,038</u>	<u>\$ 3,504,245</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>
Revenue and Support			
FDA transfer	\$ 1,250,000	\$ -	\$ 1,250,000
Contracts	920,539	-	920,539
Contributions	12,950	337,500	350,450
Sponsorships	199,694	-	199,694
Gala income	92,750	-	92,750
Interest income	35,993	-	35,993
Released from restrictions	<u>505,046</u>	<u>(505,046)</u>	<u>-</u>
Total revenue and support	<u>3,016,972</u>	<u>(167,546)</u>	<u>2,849,426</u>
Expenses			
Programs	<u>2,160,296</u>	<u>-</u>	<u>2,160,296</u>
Supporting services:			
Management and general	208,030	-	208,030
Development	152,921	-	152,921
Costs of direct benefits to donors	<u>69,956</u>	<u>-</u>	<u>69,956</u>
Total supporting services	<u>430,907</u>	<u>-</u>	<u>430,907</u>
Total expenses	<u>2,591,203</u>	<u>-</u>	<u>2,591,203</u>
Change in Net Assets	425,769	(167,546)	258,223
Net Assets, beginning of year	<u>2,253,793</u>	<u>577,136</u>	<u>2,830,929</u>
Net Assets, end of year	<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 Functional Expenses
For the Year Ended December 31, 2020

	Programs	Supporting Services			Total Expenses
		Management and General	Development	Costs of Direct Benefits to Donors	
Salaries and fringe benefits	\$ 1,256,113	\$ 98,904	\$ 227,611	\$ -	\$ 1,582,628
Professional services	24,005	827	1,075	51,158	77,065
Office and communication	70,495	12,351	16,041	-	98,887
Occupancy	114,684	26,291	14,696	-	155,671
Travel, meetings, and conferences	2,482,569	79,659	17,169	10,843	2,590,240
Total Expenses	\$ 3,947,866	\$ 218,032	\$ 276,592	\$ 62,001	\$ 4,504,491

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		Costs of Direct Benefits to Donors	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	218	135,407
Occupancy	103,406	10,735	9,099	-	123,240
Travel, meetings, and conferences	32,531	2,134	1,809	69,738	106,212
Total Expenses	\$ 2,160,296	\$ 208,030	152,921	\$ 69,956	\$ 2,591,203

See accompanying notes.

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

Statements of Cash Flows
For the Years Ended December 31, 2020 and 2019

	<u>2020</u>	<u>2019</u>
Cash Flows from Operating Activities		
Change in net assets	\$ 415,093	\$ 258,223
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation and amortization	55,809	43,137
Change in operating assets and liabilities:		
(Increase) decrease in:		
Grants and contributions receivable	(479,191)	(66,676)
Contracts receivable	(314,237)	(91,429)
Accrued interest receivable	13,584	(8,721)
Prepaid expenses and other assets	(16,407)	(12,618)
Increase (decrease) in:		
Accounts payable and accrued expenses	704,325	(18,129)
Contracts payable – data partners	230,792	303,850
Deferred contracts revenue	(359,741)	367,195
Deferred rent and tenant improvement allowance	(13,609)	(10,079)
Net cash provided by operating activities	<u>236,418</u>	<u>764,753</u>
Cash Flows from Investing Activities		
Purchases of property and equipment	(20,599)	(76,338)
Purchases of certificates of deposit	(35,365)	(2,027,273)
Redemption on maturities of certificates of deposit	<u>390,000</u>	<u>25,253</u>
Net cash provided by (used in) investing activities	<u>334,036</u>	<u>(2,078,358)</u>
Net Increase (Decrease) in Cash	570,454	(1,313,605)
Cash, beginning of year	<u>308,782</u>	<u>1,622,387</u>
Cash, end of year	<u>\$ 879,236</u>	<u>\$ 308,782</u>

See accompanying notes.

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

Notes to Financial Statements
December 31, 2020 and 2019

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 as follows:

- *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- (or certain grantor-) imposed restrictions that are met either by actions of the Foundation or by the passage of time.

Certificates of Deposit

At December 31, 2020 and 2019, 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, 2020 and 2019

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 and contributions 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, 2020 and 2019.

Contracts Receivable

Contracts receivable consist of amounts due under contracts, and are stated at their net realizable value. No allowance for doubtful accounts is recorded, as management considers all amounts to be fully collectible.

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.

Contracts Payable – Data Partners

Contracts are recorded as an expense and liability at the point in time that contractual obligations are met or qualifying expenses have occurred.

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

Notes to Financial Statements
December 31, 2020 and 2019

2. Summary of Significant Accounting Policies (continued)

Revenue Recognition

Revenue Accounted for as Contracts with Customers

Revenue is recognized when the Foundation satisfies a performance obligation by transferring a promised good to, or performing a service for, a customer. The amount of revenue recognized reflects the consideration the Foundation expects to receive in exchange for satisfying distinct performance obligations. If a performance obligation does not meet the criteria to be considered distinct, the Foundation combines it with other performance obligations until a distinct bundle of goods or services exists. Fees or amounts received in advance of satisfying contractual performance obligations are reflected as deferred revenue in the statements of financial position. Revenue is recognized either over time or at the point in time that contractual obligations are met.

Specifically, for the various types of contracts, the Foundation recognizes revenue as follows:

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 Innovation in Medical Evidence Development and Surveillance (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. Contracts received during the year wherein the Foundation has not yet completed its obligation as stipulated are recorded as deferred contracts revenue until the Foundation has discharged its designated obligations.

Special events in which a portion of the gross proceeds paid by the participant represents payment for the direct cost of the benefits received by the participant at the event. All proceeds received are recorded as special events revenues in the accompanying statements of activities. Revenue is recognized on the date of the event, which is the date the Foundation expects to be entitled to consideration in exchange for attending the event.

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

Notes to Financial Statements
December 31, 2020 and 2019

2. Summary of Significant Accounting Policies (continued)

Revenue Recognition (continued)

Revenue Accounted for in Accordance with Contribution Accounting

Cost Recovery Grants – the terms under which these grants are awarded provide for reimbursement of actual expenditures during the grant period. These funds are received in either predetermined installments or increments, based upon expenses incurred. Accordingly, grant income is recognized as allowable expenditures are incurred. Any excess or deficiency of cash receipts over expenditures incurred is reported as refundable advances or grants receivable in the statements of financial position. *Conditional grants* are recognized as revenue when the conditions are met and qualified expenses are incurred. Typically, federal and state contracts and grants are conditioned upon certain performance requirements and the incurrence of allowable qualifying expenses. Costs incurred in excess of cash received are reflected as grants receivable in the accompanying statements of financial position. Amounts received in advance are reported as refundable advances upon receipt, and recognized as revenue as conditions are met and qualified expenses are incurred.

Contributions are reported as restricted support if received with donor or grantor stipulations that limit the use of the donated assets. When a donor restriction expires, that is, when a stipulated time restriction ends or purpose restriction is accomplished, 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.

Sponsorships that are nonreciprocal are recognized as contributions. For contributions, revenue is recognized when a contribution becomes unconditional. Typically, sponsorship agreements contain a right of return or right of release from obligation should the sponsored event not take place. As such, the Foundation recognizes revenue for these conditional contributions when the related event is conducted.

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

Notes to Financial Statements
December 31, 2020 and 2019

2. Summary of Significant Accounting Policies (continued)

Advertising Costs

Advertising costs are expensed as incurred, and approximated \$8,423 and \$25,473 during the years ended December 31, 2020 and 2019, 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.

Recently Issued Accounting Pronouncement

In February 2016, the FASB issued Accounting Standards Update 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 2022. Management continues to evaluate the potential impact of this update on the Foundation's financial statements.

Reclassifications

Certain amounts in the 2019 financial statements have been reclassified to conform to the 2020 presentation. These reclassifications have no effect on the change in net assets previously reported.

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

Notes to Financial Statements
December 31, 2020 and 2019

2. Summary of Significant Accounting Policies (continued)

Subsequent Events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through April 28, 2021, the date the financial statements were available to be issued.

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, 2020 and 2019, the Foundation received 35% and 45%, 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, 2020 and 2019, reduced by amounts that are not available to meet general expenditures within one year of the statements 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, 2020 and 2019

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>2020</u>	<u>2019</u>
Cash	\$ 879,236	\$ 308,782
Certificates of deposit	3,026,785	3,381,420
Grants and contributions receivable	545,867	66,676
Contracts receivable	441,971	127,734
Accrued interest receivable	156	13,740
Less: restricted by donors with purpose restrictions	<u>(219,038)</u>	<u>(409,590)</u>
Total available for general expenditures	<u>\$ 4,674,977</u>	<u>\$ 3,488,762</u>

5. Property and Equipment

Property and equipment consists of the following at December 31:

	<u>2020</u>	<u>2019</u>
Furniture and fixtures	\$ 51,416	\$ 51,416
Website	199,876	184,651
Computer equipment and software	<u>33,057</u>	<u>27,683</u>
Total property and equipment	284,349	263,750
Less: accumulated depreciation and amortization	<u>(198,702)</u>	<u>(142,893)</u>
Property and equipment, net	<u>\$ 85,647</u>	<u>\$ 120,857</u>

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

Notes to Financial Statements
December 31, 2020 and 2019

6. Net Assets With Donor Restrictions

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

	2020	2019
Evidence Accelerator	\$ 131,870	\$ -
Expanded Access	62,168	133,989
COVID-19 Pharmacy	25,000	-
Innovation in Medical Evidence Development and Surveillance	-	275,601
Total net assets with donor restrictions	<u>\$ 219,038</u>	<u>\$ 409,590</u>

The *Evidence Accelerator* program supports research to gather real-world data and generate evidence regarding the performance of COVID-19 diagnostic and antibody tests.

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 *COVID-19 Pharmacy* program supports projects focused on digital health and lessons learned during the COVID-19 pandemic.

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.

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, 2020 and 2019 was \$155,671 and \$123,240, respectively.

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

Notes to Financial Statements
December 31, 2020 and 2019

7. Operating Lease (continued)

Future minimum lease payments are as follows for the years ending December 31:

2021	\$	135,518
2022		<u>69,623</u>
Total future minimum lease payments	\$	<u><u>205,141</u></u>

8. Pension Plan

The Foundation adopted a 401(k) Profit Sharing Plan effective on January 1, 2015 and amended on May 1, 2020, in which all employees aged 21 or older are eligible to participate. The Foundation made a safe harbor non-elective contribution and a matching contribution for the years ended December 31, 2020 and 2019. Contributions to the plan for the years ended December 31, 2020 and 2019 totaled \$60,675 and \$38,532, respectively.

9. 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, 2020 and 2019, 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.