

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

Financial Statements
Including Uniform Guidance Reports
and Independent Auditors' Report

December 31, 2021 and 2020

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

Financial Statements
December 31, 2021 and 2020

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INDEPENDENT AUDITORS' REPORT

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

Report on the Audit of the Financial Statements

Opinion

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, 2021 and 2020; the related statements of activities, functional expenses, and cash flows for the years then ended; and the related notes to the financial statements.

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, 2021 and 2020, 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.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America (GAAS) and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Our responsibilities under those standards are further described in the Auditor’s Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the Foundation and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Responsibilities of Management for the Financial Statements (continued)

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Foundation's ability to continue as a going concern within one year after the date that the financial statements are available to be issued.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with GAAS and *Government Auditing Standards* will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS and *Government Auditing Standards*, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit 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 Foundation's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Foundation's ability to continue as a going concern for a reasonable period of time.

Auditor's Responsibilities for the Audit of the Financial Statements (continued)

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control-related matters that we identified during the audit.

Supplementary and Other Information

Our audit was conducted for the purpose of forming an opinion on the financial statements as a whole. The accompanying schedule of expenditures of federal awards, as required by Title 2 U.S. Code of Federal Regulations (CFR) Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, 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 accompanying supplementary information is fairly stated, in all material respects, in relation to the financial statements as a whole.

Other Reporting Required by Government Auditing Standards

In accordance with *Government Auditing Standards*, we have also issued our report dated April 27, 2022, on our consideration of the Foundation's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. The purpose of that report is solely to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the Foundation's internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the Foundation's internal control over financial reporting and compliance.



Vienna, Virginia
April 27, 2022

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

Statements of Financial Position
December 31, 2021 and 2020

	2021	2020
Assets		
Current assets:		
Cash	\$ 535,948	\$ 879,236
Certificates of deposit	3,027,633	3,026,785
Government grants receivable	407,955	462,867
Grants and contributions receivable	90,500	83,000
Contracts receivable	726,681	441,971
Accrued interest receivable	255	156
Prepaid expenses and other assets	55,376	48,524
	<hr/>	<hr/>
Total current assets	4,844,348	4,942,539
Deposits	14,032	14,032
Property and equipment, net	52,050	85,647
	<hr/>	<hr/>
Total assets	<u>\$ 4,910,430</u>	<u>\$ 5,042,218</u>
 Liabilities and Net Assets		
 Liabilities		
Accounts payable and accrued expenses	\$ 560,506	\$ 775,660
Contracts payable – data partners	582,541	620,267
Deferred contracts revenue	120,839	114,329
Deferred rent and tenant improvement allowance	10,481	27,717
	<hr/>	<hr/>
Total liabilities	1,274,367	1,537,973
	<hr/>	<hr/>
Net Assets		
Without donor restrictions	3,578,725	3,285,207
With donor restrictions	57,338	219,038
	<hr/>	<hr/>
Total net assets	3,636,063	3,504,245
	<hr/>	<hr/>
Total liabilities and net assets	<u>\$ 4,910,430</u>	<u>\$ 5,042,218</u>

See accompanying notes.

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

Statement of Activities
For the Year Ended December 31, 2021

	<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	2,725,836	-	2,725,836
Government grant	1,059,049	-	1,059,049
Contributions	38,071	-	38,071
Sponsorships	415,800	-	415,800
Gala income	12,400	-	12,400
Interest income	948	-	948
Miscellaneous income	1,144	-	1,144
Released from restrictions	161,700	(161,700)	-
Total revenue and support	<u>5,664,948</u>	<u>(161,700)</u>	<u>5,503,248</u>
Expenses			
Programs	<u>4,925,136</u>	<u>-</u>	<u>4,925,136</u>
Supporting services:			
Management and general	189,623	-	189,623
Development	188,924	-	188,924
Costs of direct benefits to donors	<u>67,747</u>	<u>-</u>	<u>67,747</u>
Total supporting services	<u>446,294</u>	<u>-</u>	<u>446,294</u>
Total expenses	<u>5,371,430</u>	<u>-</u>	<u>5,371,430</u>
Change in Net Assets	293,518	(161,700)	131,818
Net Assets, beginning of year	<u>3,285,207</u>	<u>219,038</u>	<u>3,504,245</u>
Net Assets, end of year	<u><u>\$ 3,578,725</u></u>	<u><u>\$ 57,338</u></u>	<u><u>\$ 3,636,063</u></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 Functional Expenses
For the Year Ended December 31, 2021

	Programs	Supporting Services			Total Supporting Services	Total Expenses
		Management and General	Development	Costs of Direct Benefits to Donors		
Salaries and fringe benefits	\$ 1,793,497	\$ 81,204	\$ 155,093	\$ -	\$ 236,297	\$ 2,029,794
Professional services	2,923,493	97,489	19,158	56,215	172,862	3,096,355
Occupancy	104,573	5,823	7,792	-	13,615	118,188
Office and communication	102,173	5,027	6,773	-	11,800	113,973
Travel, meetings, and conferences	1,400	80	108	11,532	11,720	13,120
Total Expenses	\$ 4,925,136	\$ 189,623	\$ 188,924	\$ 67,747	\$ 446,294	\$ 5,371,430

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 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	\$ -	\$ 326,515	\$ 1,582,628
Professional services	2,482,569	79,659	17,169	10,843	107,671	2,590,240
Occupancy	114,684	26,291	14,696	-	40,987	155,671
Office and communication	70,495	12,351	16,041	-	28,392	98,887
Travel, meetings, and conferences	24,005	827	1,075	51,158	53,060	77,065
Total Expenses	\$ 3,947,866	\$ 218,032	\$ 276,592	\$ 62,001	\$ 556,625	\$ 4,504,491

See accompanying notes.

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

Statements of Cash Flows
For the Years Ended December 31, 2021 and 2020

	2021	2020
	<u> </u>	<u> </u>
Cash Flows from Operating Activities		
Change in net assets	\$ 131,818	\$ 415,093
Adjustments to reconcile change in net assets to net cash (used in) provided by operating activities:		
Depreciation and amortization	43,812	55,809
Change in operating assets and liabilities:		
Decrease (increase) in:		
Government grants receivable	54,912	(462,867)
Grants and contributions receivable	(7,500)	(16,324)
Contracts receivable	(284,710)	(314,237)
Accrued interest receivable	(99)	13,584
Prepaid expenses and other assets	(6,852)	(16,407)
(Decrease) increase in:		
Accounts payable and accrued expenses	(215,154)	704,325
Contracts payable – data partners	(37,726)	230,792
Deferred contracts revenue	6,510	(359,741)
Deferred rent and tenant improvement allowance	(17,236)	(13,609)
	<u> </u>	<u> </u>
Net cash (used in) provided by operating activities	<u>(332,225)</u>	<u>236,418</u>
Cash Flows from Investing Activities		
Purchases of property and equipment	(10,215)	(20,599)
Purchases of certificates of deposit	(848)	(35,365)
Redemption on maturities of certificates of deposit	-	390,000
	<u> </u>	<u> </u>
Net cash (used in) provided by investing activities	<u>(11,063)</u>	<u>334,036</u>
Net (Decrease) Increase in Cash	<u>(343,288)</u>	<u>570,454</u>
Cash, beginning of year	<u>879,236</u>	<u>308,782</u>
Cash, end of year	<u><u>\$ 535,948</u></u>	<u><u>\$ 879,236</u></u>

See accompanying notes.

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

Notes to Financial Statements
December 31, 2021 and 2020

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, 2021 and 2020, the Foundation held certificates of deposit with original maturity dates greater than a period of 90 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, 2021 and 2020

2. Summary of Significant Accounting Policies (continued)

Government Grants Receivable

Government grants receivable consists of amounts to be reimbursed to the Foundation for expenses incurred under a grant from the FDA. The entire amount of government grants receivable is expected to be collected within one year, and is recorded at net realizable value at December 31, 2021 and 2020. No allowance for doubtful amounts is recorded, as management believes that all amounts are fully collectible.

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, 2021 and 2020.

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.

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

Notes to Financial Statements
December 31, 2021 and 2020

2. Summary of Significant Accounting Policies (continued)

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.

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, 2021 and 2020

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.

Advertising Costs

Advertising costs are expensed as incurred, and approximated \$15,323 and \$8,423 during the years ended December 31, 2021 and 2020, respectively.

Reclassifications

Certain amounts in the 2020 financial statements have been reclassified to conform to the 2021 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, 2021 and 2020

2. Summary of Significant Accounting Policies (continued)

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.

Subsequent Events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through April 27, 2022, the date the financial statements were available to be issued.

Subsequent to year end, on March 15, 2022, Congress approved an act to increase funding for the Foundation. The FDA shall transfer not less than \$1,250,000 and not more than \$5,000,000 to the Foundation for each fiscal year.

As discussed in Note 7, subsequent to year end, on March 23, 2022, the Foundation entered into an agreement to lease new office space in Washington, D.C., which is set to commence on July 1, 2022 and expire on June 30, 2029. The terms of the lease contain provisions for future rent increase of 2.5% per year. In addition, the terms of the lease include a 12-month rent abatement period along with a move-in allowance totaling \$41,690 as incentive to lease the space.

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

Notes to Financial Statements
December 31, 2021 and 2020

3. 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.

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, 2021 and 2020, 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.

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:

	2021	2020
Cash	\$ 535,948	\$ 879,236
Certificates of deposit	3,027,633	3,026,785
Government grants receivable	407,955	462,867
Grants and contributions receivable	90,500	83,000
Contracts receivable	726,681	441,971
Accrued interest receivable	255	156
Less: restricted by donors with purpose restrictions	(57,338)	(219,038)
Total available for general expenditures	<u>\$ 4,731,634</u>	<u>\$ 4,674,977</u>

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

Notes to Financial Statements
December 31, 2021 and 2020

5. Property and Equipment

Property and equipment consists of the following at December 31:

	2021	2020
Furniture and fixtures	\$ 51,416	\$ 51,416
Website	199,876	199,876
Computer equipment and software	43,272	33,057
Total property and equipment	294,564	284,349
Less: accumulated depreciation and amortization	(242,514)	(198,702)
Property and equipment, net	\$ 52,050	\$ 85,647

6. Net Assets With Donor Restrictions

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

	2021	2020
Expanded Access	\$ 57,338	\$ 62,168
Evidence Accelerator	-	131,870
PhRMA/COVID-19	-	25,000
Total net assets with donor restrictions	\$ 57,338	\$ 219,038

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

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

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

Notes to Financial Statements
December 31, 2021 and 2020

7. Commitments and Contingencies

Operating Leases

The Foundation is leasing an office space in Washington, D.C., which commenced on December 31, 2016 and is scheduled to expire on June 30, 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, 2021 and 2020 was \$118,188 and \$155,671, respectively.

Subsequent to year end, on March 23, 2022, the Foundation entered into an agreement to lease new office space in Washington, D.C., which is set to commence on July 1, 2022 and expire on June 30, 2029. The terms of the lease contain provisions for future rent increase of 2.5% per year. In addition, the terms of the lease include a 12-month rent abatement period along with a move-in allowance totaling \$41,690 as incentive to lease the space.

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

2022	\$	69,623
2023		137,806
2024		279,052
2025		286,014
2026		293,164
Thereafter		<u>764,407</u>
Total future minimum lease payments	\$	<u><u>1,830,066</u></u>

Government Grants

Funds received from federal and other government agencies are subject to an audit under the provisions of the grant agreements. The ultimate determination of amounts received under these grants is based upon the allowance of costs reported to and accepted by the oversight agencies. Until such grants are completed, a potential contingency exists to refund any amounts received in excess of allowable costs. Management is of the opinion that no material liability exists.

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

Notes to Financial Statements
December 31, 2021 and 2020

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, 2021 and 2020. Contributions to the plan for the years ended December 31, 2021 and 2020 totaled \$88,229 and \$60,675, 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, 2021 and 2020, 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.

**SUPPLEMENTARY SCHEDULE AND REPORTS REQUIRED
BY THE UNIFORM GUIDANCE**

**INDEPENDENT AUDITORS' REPORT ON INTERNAL CONTROL OVER
FINANCIAL REPORTING AND ON COMPLIANCE AND OTHER MATTERS
BASED ON AN AUDIT OF FINANCIAL STATEMENTS PERFORMED IN
ACCORDANCE WITH *GOVERNMENT AUDITING STANDARDS***

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

We have audited, in accordance with the auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of Reagan-Udall Foundation for the Food and Drug Administration, Inc. ("the Foundation"), which comprise the statement of financial position as of December 31, 2021; the related statements of activities, functional expenses, and cash flows for the year then ended; and the related notes to the financial statements, and have issued our report thereon dated April 27, 2022.

Report on Internal Control over Financial Reporting

In planning and performing our audit of the financial statements, we considered the Foundation's internal control over financial reporting ("internal control") as a basis for designing audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of the Foundation's internal control. Accordingly, we do not express an opinion on the effectiveness of the Foundation's internal control.

A *deficiency in internal control* exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A *material weakness* is a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected, on a timely basis. A *significant deficiency* is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Report on Internal Control over Financial Reporting (continued)

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses or significant deficiencies may exist that were not identified.

Report on Compliance and Other Matters

As part of obtaining reasonable assurance about whether the Foundation's financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the financial statements. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards*.

Purpose of this Report

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the organization's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the organization's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.



Vienna, Virginia
April 27, 2022

**INDEPENDENT AUDITORS' REPORT ON COMPLIANCE FOR EACH
MAJOR PROGRAM AND ON INTERNAL CONTROL OVER COMPLIANCE
REQUIRED BY THE UNIFORM GUIDANCE**

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

Report on Compliance for Each Major Federal Program

Opinion on Each Major Federal Program

We have audited Reagan-Udall Foundation for the Food and Drug Administration Inc.'s ("the Foundation") compliance with the types of compliance requirements identified as subject to audit in the *OMB Compliance Supplement* that could have a direct and material effect on each of the Foundation's major federal programs for the year ended December 31, 2021. The Foundation's major federal programs are identified in the summary of auditor's results section of the accompanying schedule of findings and questioned costs.

In our opinion, the Foundation complied, in all material respects, with the types of compliance requirements referred to above that could have a direct and material effect on each of its major federal programs for the year ended December 31, 2021.

Basis for Opinion on Each Major Federal Program

We conducted our audit of compliance in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and the audit requirements of Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* ("Uniform Guidance"). Our responsibilities under those standards and the Uniform Guidance are further described in the Auditor's Responsibilities for the Audit of Compliance section of our report.

Basis for Opinion on Each Major Federal Program (continued)

We are required to be independent of the Foundation and to meet our other ethical responsibilities, in accordance with relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion on compliance for each major federal program. Our audit does not provide a legal determination of the Foundation's compliance with the compliance requirements referred to above.

Responsibilities of Management for Compliance

Management is responsible for compliance with the requirements referred to above and for the design, implementation, and maintenance of effective internal control over compliance with the requirements of laws, statutes, regulations, rules, and provisions of contracts or grant agreements applicable to the Foundation's federal programs.

Auditor's Responsibilities for the Audit of Compliance

Our objectives are to obtain reasonable assurance about whether material noncompliance with the compliance requirements referred to above occurred, whether due to fraud or error, and express an opinion on the Foundation's compliance based on our audit. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance will always detect material noncompliance when it exists. The risk of not detecting material noncompliance resulting from fraud is higher than for that resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Noncompliance with the compliance requirements referred to above is considered material if there is a substantial likelihood that, individually or in the aggregate, it would influence the judgment made by a reasonable user of the report on compliance about the Foundation's compliance with the requirements of each major federal program as a whole.

In performing an audit in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material noncompliance, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the Foundation's compliance with the compliance requirements referred to above and performing such other procedures as we considered necessary in the circumstances.

Auditor's Responsibilities for the Audit of Compliance (continued)

- Obtain an understanding of the Foundation's internal control over compliance relevant to the audit in order to design audit procedures that are appropriate in the circumstances and to test and report on internal control over compliance in accordance with the Uniform Guidance, but not for the purpose of expressing an opinion on the effectiveness of the Foundation's internal control over compliance. Accordingly, no such opinion is expressed.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and any significant deficiencies and material weaknesses in internal control over compliance that we identified during the audit.

Report on Internal Control over Compliance

A deficiency in internal control over compliance exists when the design or operation of a control over compliance does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, noncompliance with a type of compliance requirement of a federal program on a timely basis. *A material weakness in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance, such that there is a reasonable possibility that material noncompliance with a type of compliance requirement of a federal program will not be prevented, or detected and corrected, on a timely basis. *A significant deficiency in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance with a type of compliance requirement of a federal program that is less severe than a material weakness in internal control over compliance, yet important enough to merit attention by those charged with governance.

Our consideration of internal control over compliance was for the limited purpose described in the Auditor's Responsibilities for the Audit of Compliance section above and was not designed to identify all deficiencies in internal control over compliance that might be material weaknesses or significant deficiencies in internal control over compliance. Given these limitations, during our audit we did not identify any deficiencies in internal control over compliance that we consider to be material weaknesses, as defined above. However, material weaknesses or significant deficiencies in internal control over compliance may exist that were not identified.

Our audit was not designed for the purpose of expressing an opinion on the effectiveness of internal control over compliance. Accordingly, no such opinion is expressed.

Report on Internal Control over Compliance (continued)

The purpose of this report on internal control over compliance is solely to describe the scope of our testing of internal control over compliance and the results of that testing based on the requirements of the Uniform Guidance. Accordingly, this report is not suitable for any other purpose.

Rogers + Company PLLC

Vienna, Virginia
April 27, 2022

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

Schedule of Expenditures of Federal Awards
For the Year Ended December 31, 2021

Federal Grantor/Pass-Through Grantor/Program or Cluster Title	Agency or Pass- Through Grant Number	Assistance Listing Number	Federal Expenditures	Subrecipient Awards
<i>Research and Development Cluster</i>				
U.S. Department of Health and Human Services				
Direct Program – Food and Drug Administration Research				
SPARC: Supporting Patient Access, Real-world data, and critical Collaborations	3U01FD007223-01S2	93.103	\$ 562,886	\$ -
SPARC: Supporting Patient Access, Real-world data, and critical Collaborations	3U01FD007223-02S2	93.103	<u>496,163</u>	<u>-</u>
Total U.S. Department of Health and Human Services			<u>1,059,049</u>	<u>-</u>
<i>Total Research and Development Cluster</i>			<u>1,059,049</u>	<u>-</u>
Total Expenditures of Federal Awards			<u><u>\$ 1,059,049</u></u>	<u><u>\$ -</u></u>

See accompanying notes to the schedule of expenditures of federal awards.

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

Notes to the Schedule of Expenditures of Federal Awards
For the Year Ended December 31, 2021

1. Basis of Presentation

The accompanying schedule of expenditures of federal awards (SEFA) includes the federal award activity of the Foundation under the programs of the federal government for the year ended December 31, 2021. The information in the SEFA is presented in accordance with the requirements of Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). Because the SEFA presents only a selected portion of the operations of the Foundation, it is not intended to, and does not, present the financial position, changes in net assets, or cash flows of the Foundation.

2. Summary of Significant Accounting Policies

Expenditures reported in the SEFA are reported on the accrual basis of accounting. Such expenditures are recognized following the cost principles contained in the Uniform Guidance, wherein certain types of expenditures are not allowable or are limited as to reimbursement.

3. Indirect Cost Rates

The Foundation has elected to use the 10% *de minimis* indirect cost rate, which is allowed in accordance with the Uniform Guidance.

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

Schedule of Findings and Questioned Costs
For the Year Ended December 31, 2021

Section I – Summary of Independent Auditors’ Results

Financial Statements

Type of auditor’s report issued: Unmodified

Internal control over financial reporting:

- Material weakness(es) identified? _____ Yes X No
- Significant deficiency(ies) identified that are not considered to be material weaknesses? _____ Yes X None reported

Noncompliance material to financial statements noted? _____ Yes X No

Federal Awards

Internal control over the major program:

- Material weakness(es) identified? _____ Yes X No
- Significant deficiency(ies) identified that are not considered to be material weaknesses? _____ Yes X None reported

Type of auditor’s report issued on compliance for the major program: Unmodified

Any audit findings disclosed that are required to be reported in accordance with 2 CFR section 200.516(a)? _____ Yes X No

Identification of the major program:

<u>Assistance Listing Number</u>	<u>Name of Federal Program or Cluster Title</u>
93.103	Research and Development Cluster

Dollar threshold used to distinguish between type A and type B programs: \$750,000

Auditee qualified as low-risk auditee? _____ Yes X No

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

Schedule of Findings and Questioned Costs (continued)
For the Year Ended December 31, 2021

Section II – Findings – Financial Statement Audit

There were no financial statement findings reported during the fiscal year 2021 audit.

Section III – Findings and Questioned Costs – Major Federal Award Program Audit

There were no federal award findings or questioned costs reported during the fiscal year 2021 audit.

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

Corrective Action Plan
For the Year Ended December 31, 2021

There were no findings for the year ended December 31, 2021, and therefore, a corrective action plan was not needed.

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

Schedule of Prior Audit Findings
For the Year Ended December 31, 2021

The Foundation did not qualify for a Uniform Guidance audit in 2020. Therefore, there were no findings reported for the 2020 audit.