

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

Financial Statements
Including Uniform Guidance Reports
and Independent Auditor's Report

December 31, 2022 and 2021

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

Financial Statements
December 31, 2022 and 2021

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INDEPENDENT AUDITOR’S 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, 2022 and 2021; 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, 2022 and 2021, 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 audits 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 audits. 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 disclosed in Note 2 to the financial statements, the Foundation adopted Accounting Standards Update 2016-02, *Leases* (Topic 842) as of January 1, 2022. Our opinion is not modified with respect to this matter.

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.

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.

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

- 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.

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 May 15, 2023, 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
May 15, 2023

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

Statements of Financial Position
December 31, 2022 and 2021

	<u>2022</u>	<u>2021</u>
Assets		
Current assets:		
Cash	\$ 490,499	\$ 535,948
Certificates of deposit	2,775,826	3,027,633
Investments	769,732	-
Government grants receivable	584,693	407,955
Grants and contributions receivable	165,737	90,500
Contracts receivable	1,716,769	726,681
Accrued interest receivable	4,673	255
Prepaid expenses and other assets	<u>33,861</u>	<u>55,376</u>
 Total current assets	 6,541,790	 4,844,348
Deposits	26,308	14,032
Property and equipment, net	123,291	52,050
Right-of-use asset – operating lease	<u>1,453,298</u>	<u>-</u>
 Total assets	 <u><u>\$ 8,144,687</u></u>	 <u><u>\$ 4,910,430</u></u>
 Liabilities and Net Assets		
Liabilities		
Accounts payable and accrued expenses	\$ 494,346	\$ 560,506
Contracts payable – data partners	2,361,888	582,541
Deferred contracts revenue	-	120,839
Lease liability – operating lease	1,541,817	-
Deferred rent and tenant improvement allowance	<u>-</u>	<u>10,481</u>
 Total liabilities	 <u>4,398,051</u>	 <u>1,274,367</u>
 Net Assets		
Without donor restrictions	3,689,939	3,578,725
With donor restrictions	<u>56,697</u>	<u>57,338</u>
 Total net assets	 <u>3,746,636</u>	 <u>3,636,063</u>
 Total liabilities and net assets	 <u><u>\$ 8,144,687</u></u>	 <u><u>\$ 4,910,430</u></u>

See accompanying notes.

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

Statement of Activities
For the Year Ended December 31, 2022

	<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	3,614,197	-	3,614,197
Government grant	3,504,372	-	3,504,372
Contributions	40,552	-	40,552
Sponsorships	410,000	-	410,000
Gala income	4,550	-	4,550
Interest income	26,221	-	26,221
Investment return, net	(3,843)	-	(3,843)
Miscellaneous income	1,090	-	1,090
Released from restrictions	641	(641)	-
	<hr/>	<hr/>	<hr/>
Total revenue and support	8,847,780	(641)	8,847,139
	<hr/>	<hr/>	<hr/>
Expenses			
Programs	8,234,387	-	8,234,387
	<hr/>	<hr/>	<hr/>
Supporting services:			
Management and general	217,423	-	217,423
Development	181,612	-	181,612
Costs of direct benefits to donors	103,144	-	103,144
	<hr/>	<hr/>	<hr/>
Total supporting services	502,179	-	502,179
	<hr/>	<hr/>	<hr/>
Total expenses	8,736,566	-	8,736,566
	<hr/>	<hr/>	<hr/>
Change in Net Assets	111,214	(641)	110,573
Net Assets, beginning of year	3,578,725	57,338	3,636,063
	<hr/>	<hr/>	<hr/>
Net Assets, end of year	\$ 3,689,939	\$ 56,697	\$ 3,746,636
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

See accompanying notes.

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

Statement of Activities
For the Year Ended December 31, 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	<u>161,700</u>	<u>(161,700)</u>	<u>-</u>
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 Functional Expenses
For the Year Ended December 31, 2022

	Programs	Supporting Services			Total Supporting Services	Total Expenses
		Management and General	Development	Costs of Direct Benefits to Donors		
Salaries and fringe benefits	\$ 2,140,838	\$ 93,837	\$ 154,810	\$ -	\$ 248,647	\$ 2,389,485
Professional services	5,703,705	113,224	8,685	30,660	152,569	5,856,274
Office and communication	139,589	3,711	5,704	-	9,415	149,004
Occupancy	170,201	6,378	9,167	-	15,545	185,746
Travel, meetings, and conferences	80,054	273	3,246	72,484	76,003	156,057
Total Expenses	\$ 8,234,387	\$ 217,423	\$ 181,612	\$ 103,144	\$ 502,179	\$ 8,736,566

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.

Statements of Cash Flows
For the Years Ended December 31, 2022 and 2021

	<u>2022</u>	<u>2021</u>
Cash Flows from Operating Activities		
Change in net assets	\$ 110,573	\$ 131,818
Adjustments to reconcile change in net assets to net cash provided by (used in) operating activities:		
Depreciation and amortization	45,316	43,812
Net realized and unrealized loss on investments	8,233	-
Change in operating assets and liabilities:		
(Increase) decrease in:		
Government grants receivable	(176,738)	54,912
Grants and contributions receivable	(75,237)	(7,500)
Contracts receivable	(990,088)	(284,710)
Accrued interest receivable	(4,418)	(99)
Prepaid expenses and other assets	21,515	(6,852)
Deposits	(12,276)	-
Right-of-use asset – operating lease	(1,453,298)	-
Increase (decrease) in:		
Accounts payable and accrued expenses	(66,160)	(215,154)
Contracts payable – data partners	1,779,347	(37,726)
Deferred contracts revenue	(120,839)	6,510
Lease liability – operating lease	1,541,817	-
Deferred rent and tenant improvement allowance	(10,481)	(17,236)
Net cash provided by (used in) operating activities	<u>597,266</u>	<u>(332,225)</u>
Cash Flows from Investing Activities		
Purchases of property and equipment	(116,557)	(10,215)
Purchases of certificates of deposit	-	(848)
Redemption on maturities of certificates of deposit	251,807	-
Purchases of investments	<u>(777,965)</u>	<u>-</u>
Net cash used in investing activities	<u>(642,715)</u>	<u>(11,063)</u>
Net Decrease in Cash	(45,449)	(343,288)
Cash, beginning of year	<u>535,948</u>	<u>879,236</u>
Cash, end of year	<u>\$ 490,499</u>	<u>\$ 535,948</u>

See accompanying notes.

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

Notes to Financial Statements
December 31, 2022 and 2021

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, 2022 and 2021, 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, 2022 and 2021

2. Summary of Significant Accounting Policies (continued)

Investments

Investments are recorded at fair value based on quoted market prices. All realized and unrealized gains and losses, net of investment fees, are reported as a component of net investment return in the accompanying statements of activities. Cash equivalents held as a portion of the Foundation's investment portfolio are not considered to be cash for purposes of cash flows.

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, 2022 and 2021. 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, 2022 and 2021.

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.

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

Notes to Financial Statements
December 31, 2022 and 2021

2. Summary of Significant Accounting Policies (continued)

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.

Operating Lease

The Foundation records a right-of-use asset and lease liability for its operating leases. The right-of-use asset is amortized over the shorter of the lease term or the economic life of the leased asset. The associated lease liability represents the net present value of the future amounts due under the lease, calculated using a risk-free rate of return selected based on the term of the lease. For real estate leases, nonlease components are separated from the lease components for accounting purposes. The Foundation does not apply the recognition requirements under ASC Topic 842, *Leases*, to short-term leases.

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.

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

Notes to Financial Statements
December 31, 2022 and 2021

2. Summary of Significant Accounting Policies (continued)

Revenue Recognition (continued)

Revenue Accounted for as Contracts with Customers (continued)

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.

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.

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

Notes to Financial Statements
December 31, 2022 and 2021

2. Summary of Significant Accounting Policies (continued)

Revenue Recognition (continued)

Revenue Accounted for in Accordance with Contribution Accounting (continued)

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 \$34,543 and \$15,323 during the years ended December 31, 2022 and 2021, 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.

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

Notes to Financial Statements
December 31, 2022 and 2021

2. Summary of Significant Accounting Policies (continued)

Adopted Accounting Pronouncement

In February 2016, the FASB issued Accounting Standards Update (ASU) 2016-02, *Leases* (Topic 842). From a lessee perspective, the new guidance is intended to increase transparency and comparability by recognizing lease assets and lease liabilities in the statements of financial position and disclosing key information about leasing arrangements. ASU 2016-02 requires lessees to report a right-of-use asset along with a lease liability for both operating and finance leases. FASB has issued ASUs subsequent to ASU 2016-02 to further clarify and improve Topic 842.

Upon the adoption of Topic 842 on January 1, 2022, the Foundation recorded an initial right-of-use asset of \$1,559,795, an initial lease liability of \$1,537,386, and a reduction of prepaid rent of \$22,409 related to its existing office lease (see Note 8). The adoption of Topic 842 had no impact on previously reported net assets. The Foundation elected to apply practical expedients allowing it to 1) not reassess whether any expired or existing contracts previously assessed as not containing leases are, or contain, leases; 2) not reassess the lease classification for any expired or existing leases; and 3) not reassess initial direct costs for any existing leases. The Foundation also elected to apply the practical expedient to use hindsight in determining the lease term.

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.

Subsequent Events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through May 15, 2023, 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, 2022 and 2021

3. Credit Risk

Financial instruments that potentially subject the Foundation to significant concentrations of credit risk consist of cash and investments. The Foundation maintains cash deposit and transaction accounts, along with investments, with various financial institutions and these values, from time to time, exceed insurable limits under the Federal Deposit Insurance Corporation (FDIC) and Securities Investor Protection Corporation (SIPC). The Foundation has not experienced any credit losses on its cash and investments to date as it relates to FDIC and SIPC 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 or US treasury notes.

The following table reflects the Foundation's financial assets as of December 31, 2022 and 2021, 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:

	<u>2022</u>	<u>2021</u>
Cash	\$ 490,499	\$ 535,948
Certificates of deposit	2,775,826	3,027,633
Investments	769,732	-
Government grants receivable	584,693	407,955
Grants and contributions receivable	165,737	90,500
Contracts receivable	1,716,769	726,681
Accrued interest receivable	4,673	255
Less: restricted by donors with purpose restrictions	<u>(56,697)</u>	<u>(57,338)</u>
Total available for general expenditures	<u>\$ 6,451,232</u>	<u>\$ 4,731,634</u>

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

Notes to Financial Statements
December 31, 2022 and 2021

5. Property and Equipment

Property and equipment consists of the following at December 31:

	<u>2022</u>	<u>2021</u>
Furniture and fixtures	\$ 121,016	\$ 51,416
Website	199,876	199,876
Computer equipment and software	63,975	43,272
Leasehold improvements	<u>26,254</u>	<u>-</u>
Total property and equipment	411,121	294,564
Less: accumulated depreciation and amortization	<u>(287,830)</u>	<u>(242,514)</u>
Property and equipment, net	<u><u>\$ 123,291</u></u>	<u><u>\$ 52,050</u></u>

6. Investments and Fair Value Measurements

The Foundation follows FASB ASC 820, *Fair Value Measurements and Disclosures*, for its financial assets. This standard establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value measurement standards require an entity to maximize the use of observable inputs (such as quoted prices in active markets) and minimize the use of unobservable inputs (such as appraisals or other valuation techniques) to determine fair value. The categorization of a financial instrument within the hierarchy is based upon the pricing transparency of the instrument and does not necessarily correspond to the entity's perceived risk of that instrument.

The inputs used in measuring fair value are categorized into three levels. Level 1 inputs consist of unadjusted quoted prices in active markets for identical assets and liabilities and have the highest priority. Level 2 is based upon observable inputs other than quoted market prices, and Level 3 is based on unobservable inputs. Transfers between levels in the fair value hierarchy are recognized at the end of the reporting period.

In general, and where applicable, the Foundation uses quoted prices in active markets for identical assets to determine fair value. This pricing methodology applies to Level 1 investments.

Investments classified in Level 2 consist of US treasury notes, and were valued using a pricing model based on each security's term, credit quality, and stated interest rate.

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

Notes to Financial Statements
December 31, 2022 and 2021

6. Investments and Fair Value Measurements (continued)

The following table presents the Foundation's fair value hierarchy for those investments measured on a recurring basis as of December 31, 2022:

	Level 1	Level 2	Level 3	Total fair value
Cash equivalents	\$ 44,515	\$ -	\$ -	\$ 44,515
US treasury notes	-	725,217	-	725,217
Total investments	\$ 44,515	\$ 725,217	\$ -	\$ 769,732

There were no investments at December 31, 2021.

Net investment return consists of the following for the year ended December 31, 2022:

Interest and dividends	\$ 4,390
Realized and unrealized loss	<u>(8,233)</u>
Total investment return, net	<u>\$ (3,843)</u>

There was no net investment return for the year ended December 31, 2021.

7. Net Assets With Donor Restrictions

Net assets with donor restrictions consist of Expanded Access and total \$56,697 and \$57,338 at December 31, 2022 and 2021, respectively.

The *Expanded Access (EA)* program provides guidance to physicians, patients, and caregivers through its online EA Navigator. EA, also known as compassionate use, provides some patients who have serious or life-threatening diseases or conditions with access to investigational treatment not approved by the FDA.

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

Notes to Financial Statements
December 31, 2022 and 2021

8. Commitments and Contingencies

Operating Leases

The Foundation leased an office space in Washington, D.C., which commenced on December 31, 2016 and expired on June 30, 2022. The lease included an annual escalation clause, as well as various lease incentives, which were recognized on a straight-line basis in the accompanying financial statements for the year ended December 31, 2021. Deferred rent represented the unamortized portion of the tenant improvement allowance, and the cumulative difference between the actual rent paid and the straight-line rent.

On March 23, 2022, the Foundation entered into an agreement to lease new office space in Washington, D.C., which commenced on July 1, 2022 and is set to 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.

On January 1, 2022, the Foundation adopted Topic 842 and recorded a right-of-use asset and a lease liability in the accompanying statements of financial position at December 31, 2022. The lease contains no residual value guarantee and is based solely on fixed payment arrangements.

The Foundation has no short-term leases.

Occupancy expense for the years ended December 31, 2022 and 2021 was \$185,746 and \$118,188, respectively.

Supplemental qualitative information related to the operating office lease is as follows:

Operating lease costs	\$	125,119
Cash paid for amounts included in the measurement of lease liability – operating cash flows	\$	36,600
Right-of-use asset obtained in exchange for lease obligations	\$	1,559,795
Weighted-average remaining lease term (in years)		7.1
Weighted-average discount rate		2.92%

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

Notes to Financial Statements
December 31, 2022 and 2021

8. Commitments and Contingencies (continued)

Operating Leases (continued)

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liability, and a reconciliation to present value of lease liability as of December 31:

2023	\$	92,430
2024		279,052
2025		286,014
2026		293,164
2027		300,501
Thereafter		<u>463,905</u>
Total minimum lease payments		1,715,066
Less: discount to present value at 2.92%		<u>(173,249)</u>
Present value of operating lease liability	\$	<u>1,541,817</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.

9. 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, 2022 and 2021. Contributions to the plan for the years ended December 31, 2022 and 2021 totaled \$107,380 and \$88,229, respectively.

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

Notes to Financial Statements
December 31, 2022 and 2021

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, 2022 and 2021, 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 AUDITOR’S 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, 2022; 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 May 15, 2023.

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
May 15, 2023

INDEPENDENT AUDITOR’S 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, 2022. 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, 2022.

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
May 15, 2023

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

Schedule of Expenditures of Federal Awards
For the Year Ended December 31, 2022

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	\$ 5,055	\$ -
SPARC: Supporting Patient Access, Real-world data, and critical Collaborations	3U01FD007223-02S5	93.103	2,822,113	-
SPARC: Supporting Patient Access, Real-world data, and critical Collaborations	3U01FD007223-03S1	93.103	529,301	-
RACE: Real-World Accelerator to evolve the standard of Care and Engagement in clinical studies	1U01FD007779-01	93.103	<u>147,903</u>	<u>-</u>
Total U.S. Department of Health and Human Services			<u>3,504,372</u>	<u>-</u>
Total Research and Development Cluster			<u>3,504,372</u>	<u>-</u>
Total Expenditures of Federal Awards			<u><u>\$ 3,504,372</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, 2022

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, 2022. 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 on 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 Rate

The Foundation has elected to use the 10% *de minimis* indirect cost rate, as allowed under 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, 2022

Section I – Summary of Auditor’s 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, 2022

Section II – Findings – Financial Statement Audit

There were no financial statement findings reported during the 2022 audit.

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

There were no findings or questioned costs over major federal awards reported during the 2022 audit.

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

Corrective Action Plan
For the Year Ended December 31, 2022

There were no findings for the year ended December 31, 2022, 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, 2022

There were no findings or questioned costs reported for the December 31, 2021 audit.