MEMORANDUM

DATE: *February 18, 2014*

TO: *Board of County Commissioners*

FROM: *Bill Taylor, Procurement Manager*

VIA: *Katherine Miller, County Manager*
Jeff Trujillo, ASD Director
PennyEllis-Green, Growth Management Director

ITEM AND ISSUE: *BCC Meeting February 25, 2014*

**REQUESTING BCC APPROVAL FOR A WAIVER FROM SECTION 1 OF ORDINANCE 2012-6 TO PURCHASE PROFESSIONAL IT SERVICES UTILIZING THE EXISTING STATE PRICE AGREEMENT WITH BOHANNON-HUSTON, INC. FOR THE 2014 SANTA FE COUNTY TERRAIN MAPPING AND ORTHOPHOTOGRAPHY PROJECT. (*Bill Taylor, Purchasing/Penny Ellis-Green, Growth Management)*

Issue:
Bohannan-Huston, Inc. currently provides terrain data and orthophotography services pursuant to the State of New Mexico State Purchasing Price Agreement, Contract No. 10-000-00-00051 BS, Professional Engineering Services (PES) and Construction Management GIS (Environmental Services) Information Technology.

Pursuant to 13-1-129 (A), (2) NMSA 1978, **Procurement under existing contracts**, of the State Procurement Code, a local public body may procure services by utilizing existing State Price Agreements.

Background:
Santa Fe County uses orthophotography and terrain data to support County business functions including real property assessment, terrain management, County land development compliance, project and infrastructure planning, and land use and community planning activity. The County terrain data has not been systematically updated since 2001 and the most recent orthophotographs of Santa Fe County were completed in 2008. Updating this data/information/photography will support the production of accurate and high resolution orthophotographs for the next 10-15 years.

Accurate terrain data and orthophotography are seasonally and environmentally sensitive in that they are best acquired and completed during "leaf-off, no snow" conditions.

The current FY14 budget authority is $600,000 for this portion of the project which is the acquisition phase and preliminary processing of the orthophotography phase. Tentative budget authority for FY15 is an additional $600,000 (pending BCC approval of subsequent budget request) to complete the digital terrain model (DTM), for a total estimated project cost of $1.2 million dollars.

Recommendation:
Purchasing Division and Growth Management Department recommend that the Board of County Commissioners approve a waiver of Section 1 of Ordinance 2012-6 to allow purchase from a Statewide Price Agreement and authorizes the County Manager to execute a Professional Services Agreement between the County and Bohannan-Huston, Inc. for Terrain Mapping and Orthophotography Project services for a project cost not to exceed $600,000.00.

Santa Fe County 2014 Regional LiDAR Project
Proposed Scope of Work

Summary

Santa Fe County is seeking responses to this RFP from qualified Contractors to acquire and process light detection and ranging (LiDAR) data for approximately **2,600 to 3,400** square miles within north central New Mexico. The project area of interest is made up of urbanized areas, surface irrigated riparian areas, badlands, high desert plains and mountainous landscapes. Elevation ranges from 5,400 to 13,000 feet above mean sea level.

Purposes

This LiDAR project is undertaken to support activities such as the following (this list is not exhaustive):

- Urban, community and regional planning
- Project and infrastructure planning
- Project reporting
- Floodplain mapping
- Stormwater management
- Vegetation analysis
- Change detection
- Initial project reviews

Geographic Extent

The project area is described on *Exhibit A - Proposed LiDAR Project Area.* The project includes a minimum area of approximately 2,600 square miles that may be expanded pending additional cooperator participation as well as final per unit acquisition and production costs. The minimum project area covers the entirety of Santa Fe County, New Mexico and extends outward to capture the entirety of several hydrological unit sub-basins.

Data coverage areas shall be exceeded by a buffer of 300 feet (±10 feet) on all sides, beyond any stated project boundary.

It should be noted that Santa Fe County will also fly 6-inch resolution imagery in these areas in spring 2014. The LiDAR derived products (e.g., bare earth surface) requested as part of this RFP must support orthorectification of this imagery, and image and LiDAR flight schedules have to be coordinated by the Contractor accordingly.

Services to be Rendered

Overview

In general terms, the collection, production and delivery of the products and services to be provided by the Contractor include the following:

- Raw LIDAR data;
- Classified LiDAR point clouds;
- TIN-based DTMs;
- Bare-earth DEM;
- Breaklines;
- Control points;
- Contours;
- Documentation of system calibration, collection and processing methods, survey methods, QA, Accuracy Testing and Reporting, and metadata;

Project management services that include progress tracking and regular communication to the Santa Fe County Project Manager and the Santa Fe County orthoimagery vendor (when requested).

Weekly reports of collection progress.

The Contractor shall furnish all materials, supervision, labor, equipment, and transportation, unless otherwise specified in this RFP to complete the following tasks and deliver the listed products.

LIDAR collection and data processing shall adhere at minimum to the USGS, National Geospatial Program, Lidar Base Specification Version 1.0, (2012) standard, as posted at http://pubs.usgs.gov/tm/11b4/.

In addition the Contractor shall adhere to FEMA, Procedure Memorandum No. 61 - Standards for Lidar and Other High Quality Digital Topography, as posted at http://www.fema.gov/media-library/assets/documents/19742?id=4345, as applicable to "Hydro-Enforcement".

Both standards are herewith incorporated into this RFP by this reference.

Respondents are invited to present alternative proposals that cause improvements in the horizontal and/or vertical accuracies of the products, even if these proposals exceed stated standards. Each such alternative proposal shall be brief, concentrating mainly on the specific aspects that cause such improvements, plus the impact on pricing.

Respondent shall describe the following in their response: LiDAR spot size and spot spread, number of returns, intensity values, NPS, data voids, spatial distribution, scan angle, accuracy, overlap, collection conditions etc.)

Clarification, emphasis on and additions to these specifications are noted below.

LIDAR Collection Requirements

Nominal Pulse Spacing/Point Density

The LiDAR data for the entire project area are to be collected at a Nominal Pulse Spacing (NPS) of 0.7 meter or less. This corresponds to a point density of approximately 2 points per square meter. In general, this target NPS of 0.7 meter or less should not be achieved through swath overlap or multiple passes.

Raw Point Cloud Requirements:

Format: Fully compliant LAS v1.3 format
If full waveform data are collected, delivery of the waveform packets is required. LAS v1.3 deliverables with waveform data are to use external auxiliary files with the extension .wdp for the storage of waveform packet data..

Georeference information shall be included in all LAS file headers.

GPS times are to be recorded as Adjusted GPS Time, at a precision sufficient to allow unique timestamps for each return.

Intensity values shall retain native radiometric resolution. The signal strength (intensity) of each return pulse shall be recorded.

Signal Returns: The LiDAR system shall be configured to collect multiple returns per pulse, with a minimum of a first return and a last return and at least one additional intermediate return (minimum 3 returns). All returns captured during acquisition shall be delivered. Return number shall be recorded. Data Voids within a single swath are not acceptable, except:

- where caused by water bodies.
- where caused by areas of low near infra-red (NIR) reflectivity such as asphalt or composition roofing.
- where appropriately filled-in by another swath.

Spatial Distribution: The spatial distribution of geometrically usable points is expected to be uniform and free from clustering. Although it is understood that LiDAR instruments do not produce regularly gridded points, collections should be planned and executed to produce a first-return point cloud that approaches a regular lattice of points, rather than a collection of widely spaced high density profiles of the terrain.

Scan Angle: For oscillating mirror LiDAR systems, the scan angle must be <= ±20 degrees from nadir or full scan angle <= 40 degrees. Otherwise, scan angle must be <= 30 degrees.

Vertical Accuracy Requirements: LIDAR shall meet or exceed the vertical accuracies as established by the National Digital Elevation Program (NDEP) guidelines and subsequently adopted by the American Society for Photogrammetry and Remote Sensing (ASPRS). As a minimum, resulting vertical project accuracies have to satisfy the following:

- For the unclassified LIDAR point cloud, using the NDEP/ASPRS methodology:
  - Fundamental Vertical Accuracy (FVA) <= 24.5 centimeters (cm) Accuracyz (ACCz), 95 percent (12.5 cm Root Mean Square Error (RMSE)z).
- For the derived DEM and TIN, using the NDEP/ASPRS methodology:
  - Fundamental Vertical Accuracy (FVA)<= 24.5 cm ACCz, 95 percent (12.5cm RMSEz);
  - Consolidated Vertical Accuracy (CVA)<= 36.3cm, 95th percentile, and
  - Supplemental Vertical Accuracy (SVA)<= 36.3 cm, 95th percentile.

Positional Accuracy Validation: The absolute and relative accuracy of the data, both horizontal and vertical, relative to known control, shall be verified prior to classification and subsequent product development. A detailed report of this validation is a required deliverable.

Relative Accuracy Requirements: Relative accuracy shall be:

<= 7cm RMSEz within individual swaths

<=10 cm RMSEz or within swath overlap (between adjacent swaths).

Accuracy Reporting: Data shall meet or exceed the National Standard for Spatial Database Accuracy (NSSDA) accuracy standards. The NSSDA standards specify that vertical accuracy be reported at the 95 percent confidence level for data tested by an independent source of higher accuracy. For example the metadata statement shall read, "Tested __ (meters, feet) vertical accuracy at 95 percent confidence level." This reporting shall include bare-earth FVA for Point Cloud Data and DEMs, plus multiple SVAs and CVA.

Control shall be based on a state-of-the-art Airborne Global Positioning/Inertial Measurement Unit or AGPS/IMU solution and processing techniques. An AGPS PDOP of 3.2 (or smaller) shall be respected during LiDAR collection.

Supplemental Ground Control in the form of differentially corrected GPS Ground Control shall be used to supplement the Airborne GPS/IMU positional accuracy (horizontal and vertical). The supplemental

control used for the LiDAR acquisition shall utilize as much of the same control as used for the orthophotography mapping portion of this project as is reasonably possible. If different Offerors are awarded the LiDAR and Orthoimagery portions of this project, then the Contractors shall coordinate to determine which control will be best used for both purposes.

Flight lines shall have a side overlap of 20-30%, as required to ensure there are no data gaps between the usable portions of the swaths. Collections in high relief terrain are expected to require greater overlap. Any data that show gaps between the geometrically usable portions of the swaths will be rejected.

Swaths: Full swaths shall be delivered - all collected points are to be delivered. Long swaths (those which result in a LAS file larger than 2GB) shall be split into segments. Each swath shall have one cross-tie at the beginning, one at the approximate center, and one at the end. Each such segment shall be regarded as a unique swath. In addition;

- Each sub-swath will retain the original File Source ID of the original complete swath.
- Points within each sub-swath will retain the Point Source ID of the original complete swath.
- Each sub-swath file will be named identically to the original complete swath, with the addition of an ordered alphabetic suffix to the name ("-a", "-b" … "-n"). The order of the named sub-swaths shall be consistent with the collection order of the points ("-a" will be the chronological beginning of the swath; "-n" will be the chronological end of the swath).
- Point families shall be maintained intact within each sub-swath.
- Sub-swaths should be broken at the edge of the scan line.
- Other swath segmentation criteria may be acceptable subject to prior approval.

Note that the above-mentioned Santa Fe County imagery collection effort will be flown in a North-South direction.

Scope of Collection: All collected swaths are to be delivered as part of the raw data deliverable. This includes calibration swaths and crossties. This in no way requires or implies that calibration swath data are to be included in product generation. All collected points are to be delivered. No points are to be deleted from the swath LAS files. Excepted from this are extraneous data outside of the buffered project area (aircraft turns, transit between the collection area and airport, transit between fill-in areas, etc.). These points may be permanently removed. Busted swaths that are being completely discarded by the vendor and re-flown do not need to be delivered.

Flight Window: Collection window shall be between the contract execution date and Fall 2014. Schedule will be determined based on aerial imagery acquisition and the method for acquisition and processing proposed by the Contractor. The collection window can be negotiated and adjusted based on the needs of the Santa Fe County 2014 aerial imagery acquisition. Change to the schedule must be agreed to by Santa Fe County and the Contractor. Atmospheric conditions shall be such that they are:

- Cloud, smoke, precipitation and fog-free between the aircraft and ground
- Snow free; very light, un-drifted snow may be acceptable in special cases, with prior approval.
- Free of water inundation.
- Vegetation is leaf-off, but not required as long as penetration is sufficient to create a bare-earth data and products at the specified accuracies

LIDAR Deliverable Requirements

Datums

The deliverables should be supplied to Santa Fe County in the following projections:

NAD83 HARN State Plane New Mexico Central (3002), US Survey Feet
UTM NAD83 HARN Zone 13, Meters

All project areas fall within one single UTM zone.

Data should reference the most recent Geoid model approved by the NGS, to two decimal places.

Classified Point Cloud:
All processing should be carried out with the understanding that all point deliverables are required to be in fully compliant LAS v1.3 format. Contractor shall deliver a classified LiDAR point cloud containing the following:

- Georeference information included in LAS header;
- Intensity values in native radiometric resolution;
- Point families shall be maintained intact through all processing before tiling. Multiple returns from a given pulse will be stored in sequential (collected) order.
- Tiled delivery, without overlap;

Classification Scheme (minimum):

- Code 1 – Processed, but unclassified
- Code 2 – Bare-earth ground
- Code 7 – Noise (low or high, manually identified, if needed)
- Code 9 – Water
- Code 10 – Ignored Ground (in proximity of breaklines)

ALL points not identified as Withheld are to be classified.
No points in the classified LAS deliverable will be assigned Class = 0.
Use of the ASPRS/LAS Overlap classification (Class=12) is prohibited.
If overlap points are required to be differentiated by the data producer or cooperating partner; the points0 must be identified using a method that does not interfere with their classification. The technique used to identify overlap must be clearly described in the project metadata files.
Point classification is to be consistent across the entire project. Noticeable variations in the character, texture, or quality of the classification between tiles, swaths, lifts, or other non-natural divisions will be cause for rejection of the entire deliverable.

Note: Class 7, Noise, is included as a convenience for the data producer. It is not required that all "noise" be assigned to Class 7.

Note: Class 10, Ignored Ground, is for points previously classified as bare-earth but whose proximity to a subsequently added breakline requires that it be excluded during Digital Elevation Model (DEM) generation.

Contractor shall perform point cloud classification services to build a bare-earth and other point classes as specified for LAS format 1.3. This includes the "ignore" layer surrounding breaklines.

Hydro Flattening Requirements
All water-surface areas that are acquired shall be hydro-flattened according to the above-mentioned USGS specifications (USGS, National Geospatial Program, Lidar Base Specification Version 1.0, 2012).

Hydro-Enforcement Requirements

Santa Fe County desires to improve the spatial accuracy of its surface stream vector data layer. In order to accomplish this goal, the County requests that respondents submit cost proposals for optional hydro-enforcement work as follows:

> In areas where digital ortho photos are to be produced (see *Exhibit B - Proposed Ortho Photo Project Area*) the Contractor will construct single-line hydro feature breaklines and other breaklines as necessary to produce an improved DTM surface to support high accuracy orthorrectification. Respondents should provide per square mile costs estimates for this additional work based upon high, medium and low density stream channel presence within a given area (e.g., square mile).

Should the option to produce single-line hydro feature (stream) breaklines be exercised by Santa Fe County, the following guidelines must be met:

- All vertices along single-line stream breaklines must be at or below the immediately surrounding terrain.
- Single-line stream breaklines are not to be used to introduce cuts into the DEM at road crossings (culverts), dams, or other such features, however, elevated bridges are to be removed from the DTM.
- All breaklines used to modify the surface are to be delivered as an ESRI shapefile (PolylineZ or PolygonZ as appropriate to the type of feature represented) with the DEMs.
- Each shapefile will include properly formatted and accurate georeference information. All shapefiles must include a correct and properly formatted *.prj file.
- Breaklines must use the same coordinate reference system (horizontal and vertical) and units as the LiDAR point delivery.
- Breakline delivery may be as a continuous layer or in tiles, at the discretion of the data producer. In the case of tiled deliveries, all features must edge-match exactly across tile boundaries in both the horizontal (X-Y) and vertical (Z) spatial locations.

TIN

Contractor shall build a TIN from the point cloud and use it to generate three deliverables:

1. A non-gridded DTM - to be used for orthorectification of the project's 2014 imagery
2. A gridded DEM - suitable for use in the USGS 1/9-arc-second DEM (NED)
3. Contours, in ortho production areas only

TIN-Based Digital Terrain Models (Non-Gridded DTMs)

Contractor shall build TIN-based DTMs to be used for the orthorectification of the Santa Fe County 2014 imagery.

Bare Earth Surface (Gridded DEM)

- Contractor shall build one DEM to satisfy USGS NED (1/9-arc-second DEM) requirements for all areas;
- Delivery in an industry-standard, GIS-compatible, 32-bit floating point raster format (ERDAS .IMG preferred);
- Georeference information shall be included in raster file;
- DEM tiles will show no edge artifacts or mismatch;
- Void areas (i.e., areas outside the project boundary but within the tiling scheme) shall be coded using a unique "NODATA" value. This value shall be identified in the appropriate location within the file header;

- Vertical Accuracy of the bare earth surface raster data shall be similar (plus or minus 10%) to the one specified for the raw point cloud above. Depressions (sinks), natural or man-made, are not to be filled (as in hydro-conditioning and hydro-enforcement) except for in specified project areas;
- Water Bodies (ponds and lakes), wide streams and rivers ("double-line"), and other non-tidal water bodies shall have been hydro-flattened within the DEM, subject to the USGS specifications. The DEM will be processed and supplemented with 3D operator-generated breaklines as necessary to meet the USGS specifications.

Contours
Contractor shall cut contours as specified, using the TIN-based DTM datasets.

Contours will be generated for all project areas where digital orthophotography is produced. Contour interval ("ci") will be 2 foot isolines.
Non-crossing contour lines will be developed from the completed TIN-based DTM so that vertical accuracy is maintained (plus or minus 10%).
Every fifth contour line (10 foot isolines) shall be an attributed index contour (INDEX = 1
All contour lines shall be solid and unbroken features within each separate tile.
Elevation values are assigned to the contour lines and carried as integer attributes.

Delivery and Tiling
Contractor shall provide all deliverables that are produced from LiDAR data (other than LiDAR swaths), such as TINs, DTMs, DEMs, and contours in the formats as outlined below.

All project area boundaries are understood to include the specified buffer.

Tiles which lie completely within the project area shall be complete to the tile edges.

The deliverables should be supplied to Santa Fe County in the following manner:
- The classified point cloud data shall be delivered as tiles as UTM and State Plane datasets, as described below.
- The contour data shall be delivered as a State Plane dataset, as described below.

UTM Datasets
Tiles shall be 1500 x 1500 meters named on the even UTM lines derived from the southwest corner of each tile using the last digit of the UTM zone, the three digits of the west UTM line, and four digits from the south UTM line. For example: zwwwssss

Where z = last digit of UTM zone
www = west limit in thousands
ssss = south limit in thousands

- Tiled deliverables shall conform to the tiling scheme, without added overlap.
- Tiling scheme will be used for all tiled deliverables in this projection.
- Tiled deliverables shall edge-match seamlessly in both the horizontal and vertical.
- All tiles shall be completely filled in (even if it covers only a portion of the buffer).

State Plane Datasets
Tiles shall be 1 mile x 1 mile approximately, based upon Public Land Survey System sections, and labeled according to the Santa Fe County tiling schemes which will be provided to the contractor.
This tiling scheme will be used for all tiled deliverables.

Tiled deliverables shall edge-match seamlessly in both the horizontal and vertical, as applicable.

Control and Calibration Points
The contractor shall deliver all control and reference points used to validate the point data and derivative products. They shall be delivered in ESRI shapefile (.shp) format with associated FGDC-compliant metadata.

Extents
The contractor shall deliver a geo-referenced, digital, spatial representation of the precise extents of each delivered dataset. This should reflect the extents of the actual LIDAR source or derived product data, exclusive of Triangular Irregular Network (TIN) artifacts or raster NODATA areas. A union of tile boundaries or minimum bounding rectangle is not acceptable. An ESRI Polygon shapefile is preferred.

Documentation

Project Plan
- Delivered before the flights.
- Outlines the proposed methodology for collection and processing.
- Includes risk mitigation strategies and contingency planning.

System Calibration Report
- Delivered before the flights.

Collection Report
- Includes mission planning and flight logs.
- Includes study area PDOP, mission date, time, flight altitude, airspeed, scan angle, scan rate, laser pulse rates.
- Statistical report summarizing the results of the airborne GPS adjustment and the overall accuracy of the adjusted IMU data.

Survey Report
- A record of field work procedures.
- A record of horizontal and vertical datums utilized.

Processing Report
- Data derivation and adjustments.
- Classification information.
- Product generation methodology.
- Hydro-flattening and enforcement information.
- Any problems encountered and solutions used in resolving such problems.

QA Report
- Quality assurance procedures and results.
- Verification of vertical and positional accuracy of the point cloud and derivatives.
- Detailed explanation of the data validation process.
- Discussion of artifacts and their causes.

FGDC compliant, XML format metadata for:
- Overall project
- Each lift
- Classified point data
- Bare-Earth DEM
- TIN-based DTMs
- Breaklines
- Contours
- Control Points

Please see the USGS LIDAR Metadata Example provided in the USGS specifications above.

Independent Quality Control (QC)

The Contractor should be aware that Santa Fe County may request independent verification of the deliverables to ensure that project specifications are met. The QC party would perform the following actions:

- Estimate the vertical accuracy of the control points at the 95% confidence interval;
- Estimate the vertical accuracy of the bare-earth classification against independent check points;
- Perform system verification, laser range verification, and AGPS/IMU verification (proper PDOP, etc.);
- Check that point cloud classifications were done correctly;
- Check that flight lines were flown as planned;
- Confirm that all collected LiDAR data are covered by the resulting swaths as specified, together with the required cross-ties;
- Confirm the GPS baseline lengths;
- All files are readable in CAD and ArcGIS;
- All files are named correctly;
- Confirm that the data covers the entire project area;
- Confirm that the data has no unacceptable data voids (e.g. due to incorrect flight heights, clouds, or improper flight lines);
- Confirm that the NPS adheres to project specifications; assessment will be made against single swath, first (or applicable last) return data located within the geometrically usable center portion (typically ~90%) of each swath. In order to ensure uniform densities throughout the data set:
    - A regular grid, with cell size equal to the design NPS will be laid over the data.
    - At least 90% of the cells in the grid shall contain at least 1 LiDAR point.
    - Clustering will be tested against the 1st return only data
    - Acceptable data voids identified elsewhere in this specification are excluded.
- Confirm that the horizontal and vertical datums adhere to the project specification;
- Confirm that the projection and units adhere to the project specification;
- Confirm that the LAS files are in a consistent version and have proper header information;
- Confirm that each point in the point cloud has the appropriate attributes (GPS times, coordinates, elevation, intensity, return number, return classification);
- Confirm that all points are classified into the specified scheme;
- Ensure there are no seam lines between flight swaths;
- Ensure metadata is complete;
- Confirm that DEMs have correct names and have the correct post spacing;
- Confirm that contours are at the correct interval and are indexed and labeled. Ensure no crossing contours; and
- Ensure that hydro flattening is correct by confirming that lake and pond breaklines are a constant elevation, that streams have a continuous downstream flow (no stair steps),and water points are correctly identified.

Term

The awarded contract will begin on the date it is signed and ends, unless sooner terminated under the Terms and Conditions of the Contract or extended by a contract amendment, on June 30, 2015.

Access Agreements:

The successful Contractor shall provide written notification to the County on the number and locations of ground control points used in this project. The Contractor shall determine land ownership encompassing those locations and as required, obtain site access permission. The Contractor shall notify

landowners and coordinate with the appropriate personnel prior to on-site or over-site activities. The Contractor shall be solely responsible for the requisite filing of flight plans and obtaining appropriate permissions from the FAA and other agencies as necessary.

Option for Subsequent Partnerships

To the extent that other governmental jurisdictions are legally able to participate in cooperative purchasing endeavors, member jurisdictions may choose to directly contract with the Contractor for additional and related products independently of Santa Fe County.

In such case, the terms of the contract between the Contractor and Santa Fe County shall be honored, even though Santa Fe County will not be facilitating the additional deliverables. The vendor shall deal directly with the jurisdiction concerning payments, disputes, and other topics related to the additional products. Santa Fe County shall have no responsibility or liability to the vendor, the requesting jurisdiction or any other party in connection with any such direct purchase or performance of an additional product.

All partnerships pursued without Santa Fe County facilitation shall not interfere with the work requested through this RFP. Additional products that are independently requested are developed after deliverables for the scope of work mentioned herein are completed.

Through this Option of Subsequent Partnerships, the partners could work directly with the Santa Fe County LiDAR vendor, based on the quotes given in the pricing form, to attain that data.

Project Timeline

Below is a preliminary timeline. This is subject to change based on the timing and coordination with the aerial imagery acquisition that will be occurring in the spring and summer. A final schedule will be produced and included in the contract.

January 2014 Partners receive budget approvals, which determines if the project can begin

February 2014 Statement of Work is written; contract finalized

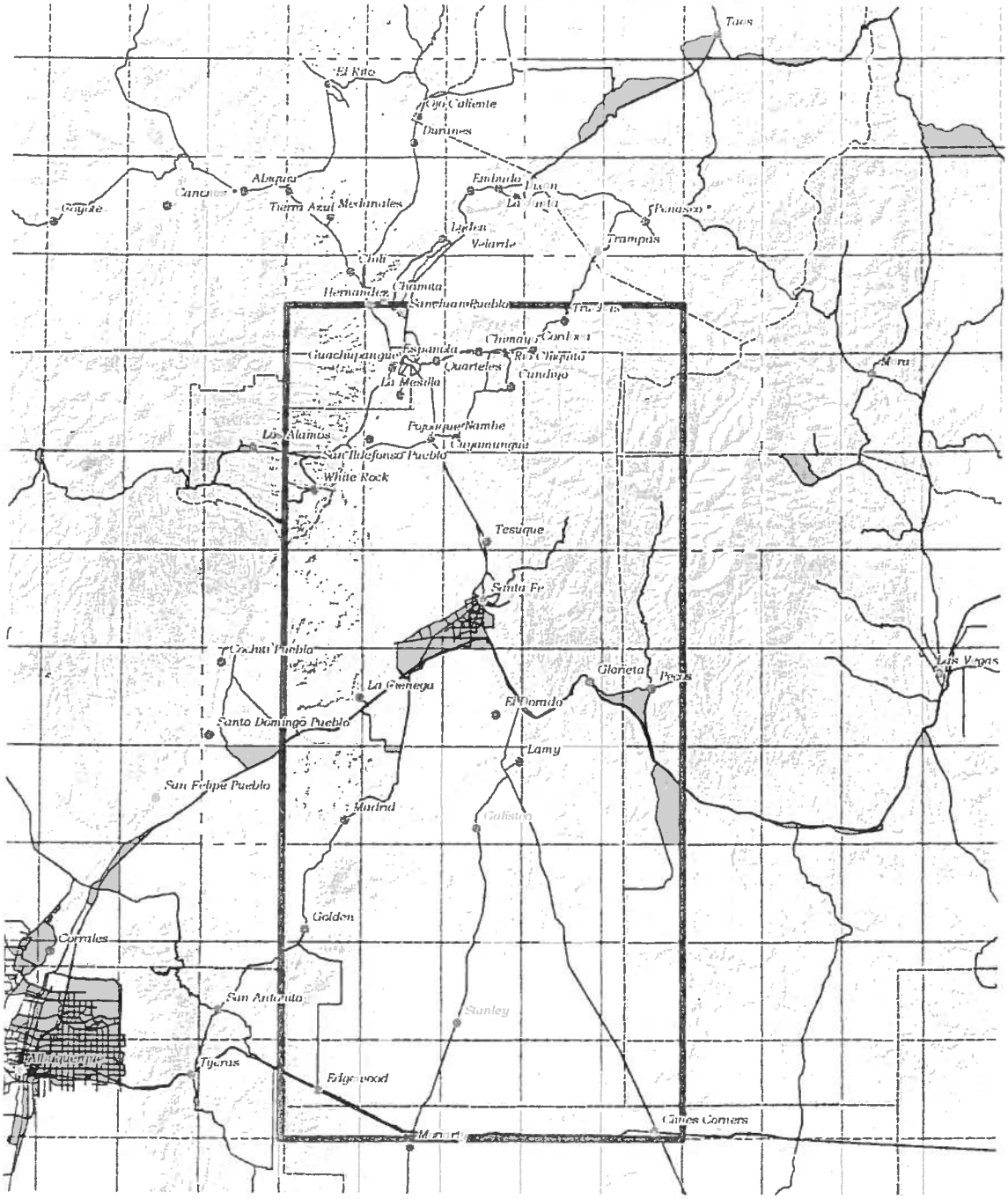
March 2014 Kick-off meeting

April - June 2014 LIDAR Acquisition (may or may not be coordinated with aerial imagery flights)

July- September 2014 LIDAR Processing

October - November 2014 All LIDAR and derivative deliverables due

Exhibit A - Proposed LiDAR Project Area



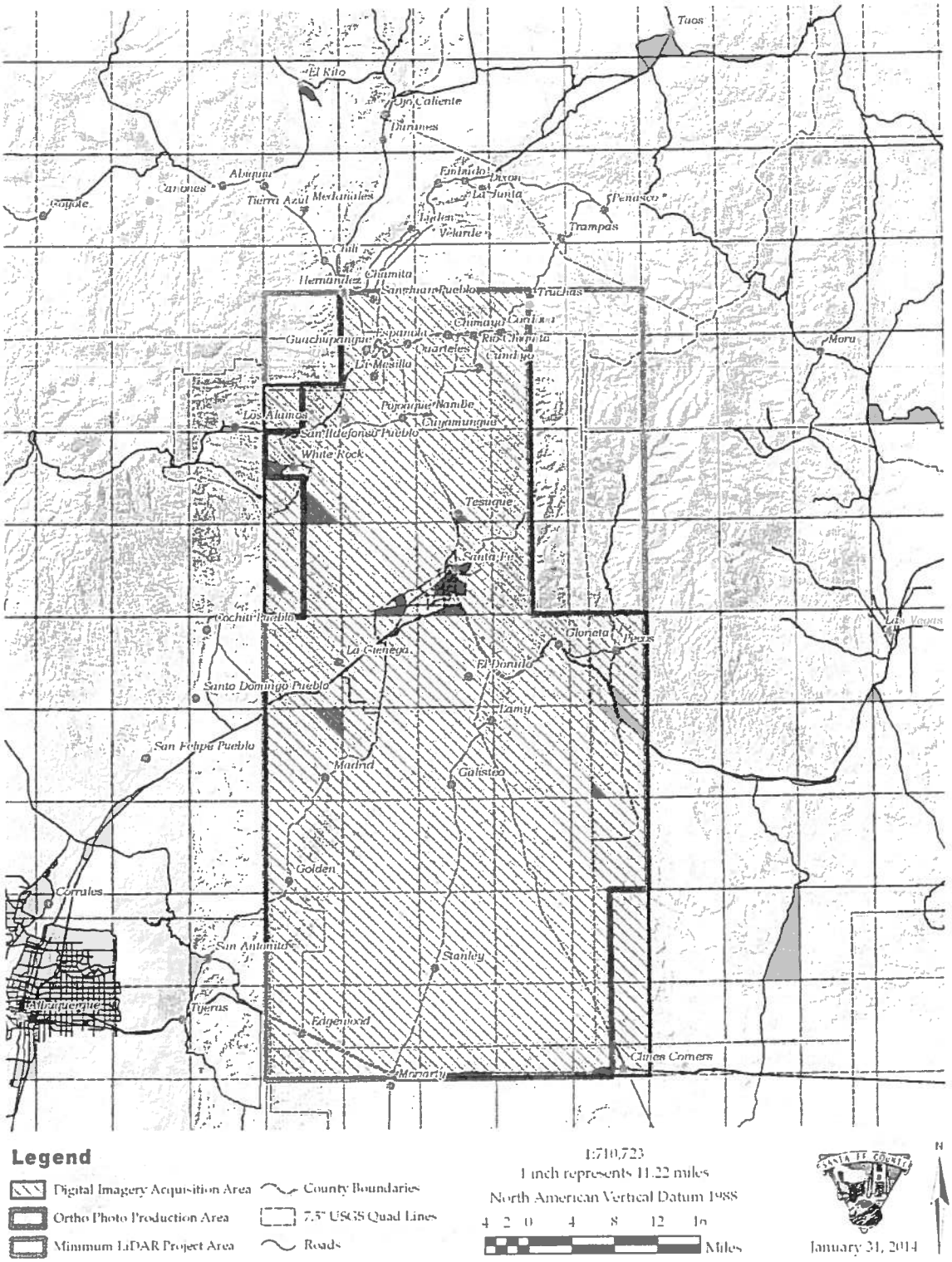
Legend

- Santa Fe County Project Area
- Proposed Maximum Project Area
- Roads
- County Boundaries
- 7.5' USGS Quad Lines

1:710,723
1 inch represents 11.22 miles
North American Vertical Datum 1988
4 2 0 4 8 12 16
Miles

January 31, 2014

Exhibit B - Proposed Ortho Photo Project Area



Santa Fe County 2014 Digital OrthoPhotography Project
Proposed Scope of Work

I. SCOPE OF SERVICES

A. GENERAL PROJECT INFORMATION

Santa Fe County ("the County") is seeking proposals from qualified firms/individuals ("Offeror") to provide the photo control survey, aerial survey, and rectification services necessary for the production of high resolution, 4-band (true color RGB with color infrared {CIR} band 4) digital orthoimagery (DOI) and optional planimetric mapping for selected areas of the County of Santa Fe for use in a Geographic Information System (GIS). The work completed for this project shall be suitable for the production of digital photogrammetric mapping meeting the specified accuracy requirements. Funding commitments from local partners may not be confirmed until actual unit-costs are provided. Project funders will retain ownership of the imagery and associated products.

Exhibits are attached to aid Offerors in both understanding the scope of this project and in formulating work plans required for proposals. *Exhibit A - Proposed LiDAR Project Area* shows the overall area of interest upon a shaded relief basemap with major roads, and cities and town. The base map illustrates the variation in the elevation in the County from approximately 5400 feet along the Rio Grande to over 13,000 feet in the Sangre de Cristo Mountains.

Acquisition Area: (see *Exhibit B - Proposed Ortho Photo Project Area*) 4-band digital imagery to be collected for the production of 0.5 foot pixel resolution capable of meeting a horizontal positional accuracy of +/- 2 feet or better. Minimum acquisition area will be approximately 2,210 square miles. Acquisition area may be expanded northward in contiguous blocks contingent upon funding commitments from local cooperators in this area.

Production Area: (see *Exhibit B - Proposed Ortho Photo Project Area*) 4-band DOI to be delivered at a 0.5 foot pixel resolution capable of meeting a 95% confidence level in horizontal positional accuracy of +/- 2 feet or better at a printed map scale of 1 inch = 100 feet.. Propose minimum production area will be approximately 2,090 square miles. Production area may be expanded northward in contiguous blocks contingent upon funding commitments from local cooperators in this area. Final production areas will ultimately be determined by per unit (square mile) costs, available budget including cooperator funding, and determination on whether to exercise optional product acquisitions (e.g., planimetric mapping, high density hydro-enforcement, NGS blue booking, etc). It is fully anticipated that funds will be available for the production of an absolute minimum of 2,000 square miles of 0.5 foot pixel resolution 4-band DOI.

Santa Fe County anticipates updating surface models with a LiDAR derived, hydro-enhanced digital terrain model (DTM) to be produced in conjunction with this digital orthoimagery project. The larger extents of the 2014 LiDAR project can be seen on both Exhibits A and B.

Proposals for the optional production of Building Footprint Planimetrics are requested for the purpose of updating and extending data derived from 1992 and 2001 projects. .

B. GROUND CONTROL SURVEY

1. General

The Contractor shall locate and establish the necessary ground control for absolute orientation of stereo models. Digital terrain models and/or digital elevation models for this orthoimagery project will be provided by the County via its selected LiDAR contractor and shall be used in the orthophoto rectifications process. It is the responsibility of the Contractor to identify and field survey the ground control needed to satisfy the orthophoto rectification process. The Offeror shall specify the preferred specifications of paneling or marking for photo identification. It is the Contractor's responsibility to provide the specifications, including placement, size, and shape of the panels to be used for the establishment of geodetic control in the rectification of the orthophotography.

Ground control shall be supplemented by Airborne Global Positioning/Inertial Measurement Unit or AGPS/IMU solution and processing techniques. An AGPS PDOP of 3.2 (or smaller) shall be respected during digital imagery collection.

2. Existing Control Stations

In order to ensure consistency with past projects, horizontal and vertical control for the aerial survey and derivative products must be based on the existing High Accuracy Reference Network (HARN). There are several HARN stations in the Santa Fe County vicinity:

Station Name	**NGS PID**	**Location**
DOT 4	AI5440	NMSHTD (NM State Highway & Trans. Dept.) General Office
SANTAIR	FO1673	Santa Fe Airport
SAF ARP	AC7065	Santa Fe Airport
I40 R8	FO0983	Interstate-40 (7 miles NW of Edgewood)
MORIAIR 2	EQ1151	Moriarty Airport
LOS ALAMOS	FO1671	LANL (Los Alamos National Labs) – Tech Area 33.

For redundancy/checking and better determination of error statistics the Contractor shall simultaneously collect data on at least two of these stations during all flights. The Contractor shall use the most up to date National Geodetic Survey (NGS) values for these stations. Wherever possible, existing 1st order control monuments shall be reoccupied and paneled as required for this project.

The supplemental control used for the orthophotography acquisition shall utilize as much of the same control as used for the LiDAR mapping portion of this project as is reasonably possible. If different Offerors are awarded the LiDAR and Orthoimagery portions of this project, then the Contractors shall coordinate to determine which control will be best used for both purposes.

3. New Control Stations

Should an Offeror find/determine that existing 1st order control is not adequate to accurately establish needed ground control, new control stations (monuments) may need to be established. The County would prefer that such new control stations not only be of 1st order accuracy but also that such new stations (monuments) be blue-booked with the NGS (National Geodetic Survey). Offerors should include cost estimates for establishing and blue-booking new 1st order control monuments with the NGS as a separate, optional cost (i.e., cost per monument).

4. Standards and Specifications

All coordinates shall be accurately referenced to the HARN New Mexico State Plane Coordinate System, Central Zone (3002), North American Datum of 1983 [(NAD83 (HARN] and to the North American Vertical Datum of 1988 (NAVD88) in units of US Survey Feet.

C. AERIAL IMAGERY

1. General

The acquisition of digital imagery shall be planned as to be capable of meeting a 95% confidence level in horizontal positional accuracy of +/- 2 feet or better at a printed map scale of 1 inch = 100 feet for the specified areas. The imagery shall be acquired in four-band (natural color RGB in band 1 to 3 and infrared in band 4).

2. Camera

The Contractor shall define what camera make and model will be used, define how the camera will be stabilized and the precision and focal length of the camera. The Contractor shall provide a certificate showing calibration within 6 months of the flight.

3. Aerial Photography and Photographic Products

4-band digital aerial photography to cover the areas of mapping as indicated on *Exhibit B - Proposed Ortho Photo Project Area*. Aerial photography shall be in conformance with specifications established by the American Society for Photogrammetry and Remote Sensing.

All aerial imagery shall be obtained during "leaf off" during April/early May 2014 and shall be undertaken:
a. With the optical axis of the camera as nearly vertical as possible and in no case shall the tilt exceed 3 degrees.
b. When atmospheric conditions are such that clear and well-defined images can be obtained. Imagery shall not be acquired when the ground is obscured by snow, clouds, cloud shadows, haze, smoke, dust and/or precipitation.
c. At the time of day when shadows caused by topographic relief, and/or sun angle will be at or near a minimum. Aerial imagery shall not be attempted when the sun angle is less than 30 degrees above the horizon. Excessive and deep shadows may be cause for rejection of photography.
d. With a minimum forward overlap in the line of flight averaging approximately 60% and a minimum of 30% sidelap, with greater overlap in steep terrain if needed to capture the bottoms of all canyons.
e. The camera tilt will not be more than 3 degrees from the vertical axis at the time of image acquisition, nor shall it exceed 5 percent between successive acquisition stations.
f. Deviation from planned flight height shall not exceed 5 percent.
h. Efforts shall be made to ensure a uniform contrast between images, with no smears, blemishes or digital artifacts.
i. Unacceptable aerial photography shall be reflown at no additional cost to the County. Reflight coverage must overlap accepted photography by at least two stereo-models. Photo center points and borders will be provided with reflight imagery in the same format as for initial imagery.

4. Photographic products

a. One set of digital "raw imagery" shall be delivered to the County in either TIFF or JPEG 2000 format. File naming convention should be according to flight line number and photo/exposure number. All targeted points shall be identified. Digital "raw imagery" shall be submitted to the County for review as soon as practicable.
b. Deliverables shall include:

- Index of photo centers in a point layer in ESRI shapefile format.
- Index of frame borders ("footprints") in a polygon layer in ESRI shapefile format. Each feature in these layers should include the date and time the frame was taken.

5. Access Agreements

The successful Contractor shall provide written notification to the County on the number and locations of ground control points used in this project. The Contractor shall determine land ownership encompassing those locations and as required, obtain site access permission. The Contractor shall notify landowners and coordinate with the appropriate personnel prior to on-site or over-site activities. The Contractor shall be solely responsible for the requisite filing of flight plans and obtaining appropriate permissions from the FAA and other agencies as necessary.

D. DIGITAL ORTHOIMAGES

Digital Orthophotos shall be produced for the area shown as "Ortho Photo Production Area on *Exhibit B - Proposed Ortho Photo Project Area*. The contrast between adjoining orthophoto images shall appear to be reasonably consistent. All linear features on the ground shall appear linear, and all bridge warping shall be eliminated in the final orthorectified images, including in the infrared band.

Digital Orthoimage files shall generally be delivered in overlapping 5500 x 5500 foot tiles centered on Public Land Survey System (PLLS) sections or projected sections. A PLSS section grid layer will be provided by the County as a guide/template for image tiling. In areas where section dimensions are longer than 5300 feet (e.g. along or adjacent to correction lines) tile size shall be adjusted to extend 200 feet beyond section lines, again centered on the PLSS sections. The need for such "special" sections should be determined prior to finalization of the contract.

Digital Orthoimagery shall also be delivered as one project-wide mosaic in ECW format. Pending commitments from other local partners, project subset mosaics may be requested for City of Santa, City of Espanola and/or Rio Arriba County portions of the project. Offerors should state whether or not production of such subset mosaics will incur additional costs, and if so, provide pricing details for project subset mosaics.

Offerors are encouraged to propose/discuss techniques which will ensure a proper mosaic of tiled imagery (e.g. tile to tile edgematching, tile to tile uniform contrast/density, reliable cross tile measurements, etc.)

Before full production is begun, the successful Offeror shall provide the County with a prototype area of at least 4 square miles for quality control review. A notice to proceed for the full project will follow if all quality control checks are satisfactory. It is the sole responsibility of the County to determine the acceptability of the orthophoto product.

File structure for the raster image files will be TIFF format with Environmental Systems Research Institute (ESRI) world files AND ECW format for each tile. File naming convention should be opTTRRSS.tif for orthos & opTTRRSS.twf for worldfiles (lower case op – where TT is Township number, RR is Range number, and SS is Section number – leading zeros where applicable – ex. op100701.tif is orthophoto for Township 10, Range 7, Section 1).

FGDC (Federal Geographic Data Committee) compliant metadata will accompany the DOI files.

E. PLANIMETRIC MAPPING

Optional planimetric mapping should be based on the DOI and shall be produced so that the position of all well-defined photogrammetrically compiled map features on the finished digital database capable of meeting a 95% confidence level in horizontal positional accuracy of +/- 2 feet or better at a printed map scale of 1 inch = 100 feet. Offerors are requested to provide pricing estimates for the collection of building footprint polygons attributed with building height for high medium and low density urbanized areas on a per square mile basis (per unit costs). Offerors shall indicate their proposed methodology and equipment to be used for compiling planimetric data.

Collection via typical stereo photogrametric methods is preferred. The County will consider alternate methods for building foot print collection and Offerors are invited to present alternative proposals for the collection of these data. Each such alternative proposal shall be brief, concentrating mainly on the specific aspects of the alternate method, plus the impact on pricing.

Regardless of collection methodology, delineation of building footprints shall be compiled as closed polygons attributed with building height and delivered to the County in an ESRI shapefile PolygonZ format. File naming convention to be determined. FGDC compliant metadata will accompany the planimetric files.

F. DELIVERABLES

The COUNTY shall receive the following items:

1. Flight plan and control layout map, both in digital and hard copy formats.
2. Digital copy of "raw imagery" on CD/ROMs or other appropriate media, with a digital index/catalog of this imagery.
3. Photo index consisting of ESRI shapefiles of photo center points and "footprint" polygons.
4. Reports on: camera calibration, ground control, analytical aerotriangulation solution(s), horizontal accuracy of the DOI, accuracy of airborne GPS, automation procedures and QC/QA measures.
5. Digital orthophotography: One set of the DOI raster image data files in both ECW and TIFF file formats and associated world files and metadata file(s) provided on an external hard drive.
6. Digital planimetric mapping of building footprints: One set of the files in an ESRI shapefile PolygonZ format with associated metadata file(s) delivered on CD/ROMs or other appropriate media.

The delivery of digital orthophotography will be in phases, based on project funding.

1. Acceptance and Rejection of Products

Acceptance: Representatives of the County will be conducting in-house reviews of all products received. These include preliminary as well as final products, hard copies, and digital products. These representatives will perform all checks in a timely and orderly manner. The County may retain other CONSULTANT(s) to support this review process for all or part of this project. The Contractor shall be responsible for correcting errors or other inconsistencies that represent noncompliance with the specifications agreed to by the Contractor and the County. In no case will the completion date jointly agreed upon by the Contractor and the County be extended without the prior written approval of the County. Acceptance criteria for the primary deliverables will be categorized into data integrity verification (including format and data structure verification) and accuracy verification. After initial checking, work increments will be categorized by the County as follows:

Accepted: Orthophotography and derived products (i.e. planimetrics, etc.) that meet specifications will be formally indicated as "Accepted". Payment for work completed will not be made until the products are accepted by the County regardless of the number of edits or degree of corrections required.

Rejected: The number and character of errors detected by the County are such that the product is returned to the Contractor without complete editing. The Project Manager will formally notify the Contractor of the REJECTED status of the product. The Offerors shall edit and correct the product for resubmittal. If, at the sole discretion of the County, there are an undue number of rejected products, the County may require the Offeror to suspend production until the problems contributing to the rejections are identified and corrected. This mechanism will be used for data sets which do not meet accuracy specifications, data integrity requirements, and/or data formatting requirements.

G. QUALITY CONTROL AND ASSURANCE

The Offeror shall provide a detailed description of the quality assurance/quality control (QA/QC) processes that will be employed in the execution of this project. T he successful Contractor shall be required to provide QA/QC reports twice; once at the time of delivery of the prototype area and also at the final delivery of the remainder of the orthophotos. Included in the QA/QC reports will be airborne GPS accuracy reports, automation procedure(s) reports and other data used in this process. This information will be used by the County to support deliverable review and acceptance.

1. Project Tracking and Reporting

It is expected that several meetings between the successful Offeror's project management staff and the County will be required during the course of the project. The Offeror shall indicate the number of visits and the milestones or approximate schedule of such visits that are planned in the course of the project. Address significant milestones including deliveries of products and any meetings, working sessions or conferences with the County.

The Offeror shall maintain procedures throughout the project for tracking and reporting progress in the photogrammetric mapping process. Initial tasks of photography and aerial triangulation will be tracked and reported as a percentage of the total. Reporting on this phase of the project will be weekly initially and monthly once a regular production schedule is being maintained. As part of the proposal response, Offerors shall submit a written description of the project tracking procedures and systems that will be employed.

H. PROJECT SCHEDULE

Offerors shall indicate a schedule for completing each of the deliverables identified in the Request for Proposal. Include the start and end dates and intermediate delivery dates for this project.

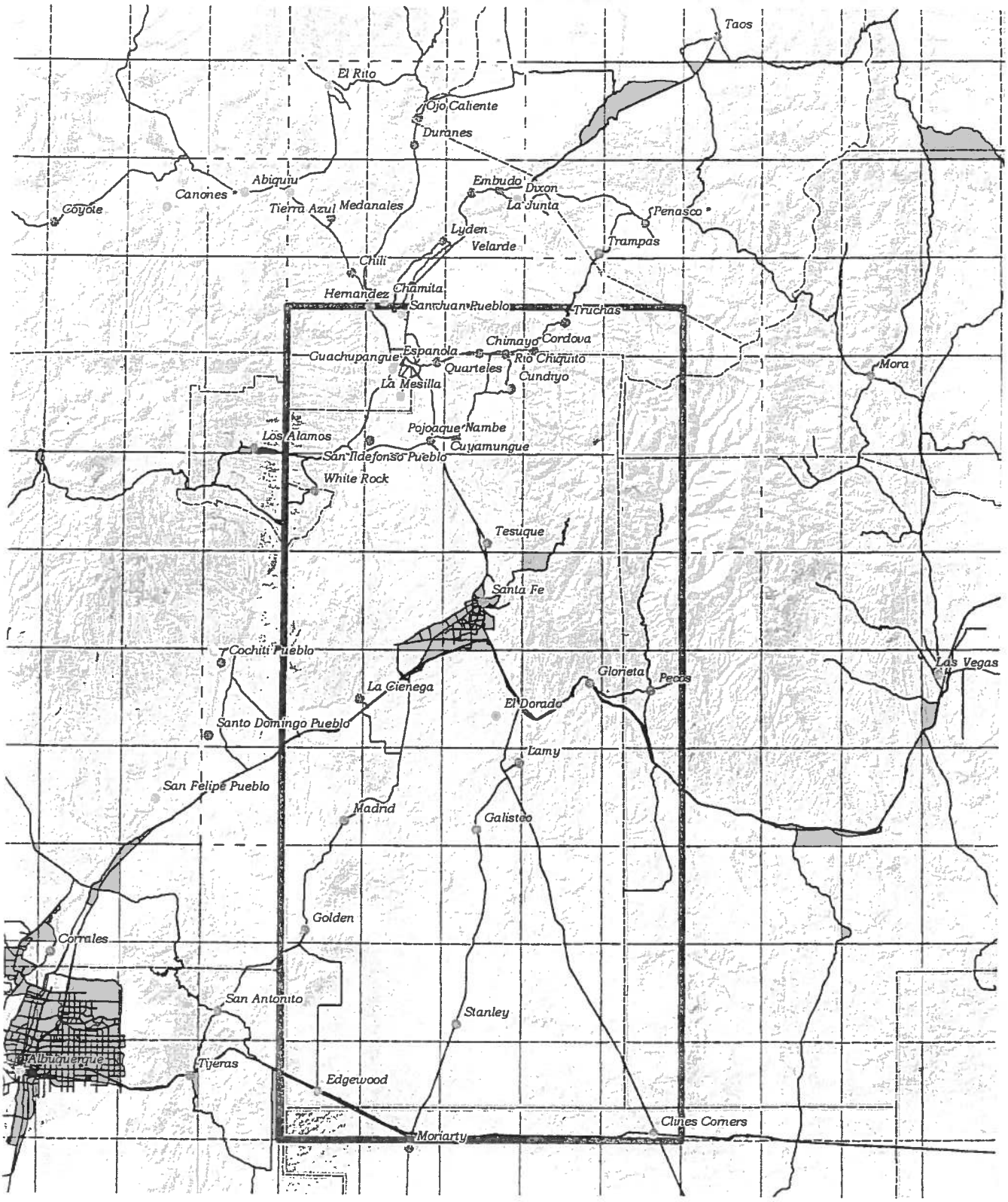
I. ALTERNATIVE PROCEDURES

1. Alternative Procedures

Due to changes, advancements, or refinements in technology, Offerors are encouraged to propose alternative means for achieving the purposes of this project. Any recently developed techniques, products, or technologies that can deliver high quality and economical performance will be considered. Responses shall address the requests and specifications contained in this RFP in addition to any alternative proposals. Any proposed alternatives must be demonstrated to be clearly superior and able to meet all project goals and requirements.

Offerors shall elaborate on any proposed exceptions. If exceptions are taken, state the general conditions involved, the exceptions taken, and alternative language.

Exhibit A - Proposed LiDAR Project Area



Legend

- Santa Fe County Project Area
- Proposed Maximum Project Area
- Roads
- County Boundaries
- 7.5" USGS Quad Lines

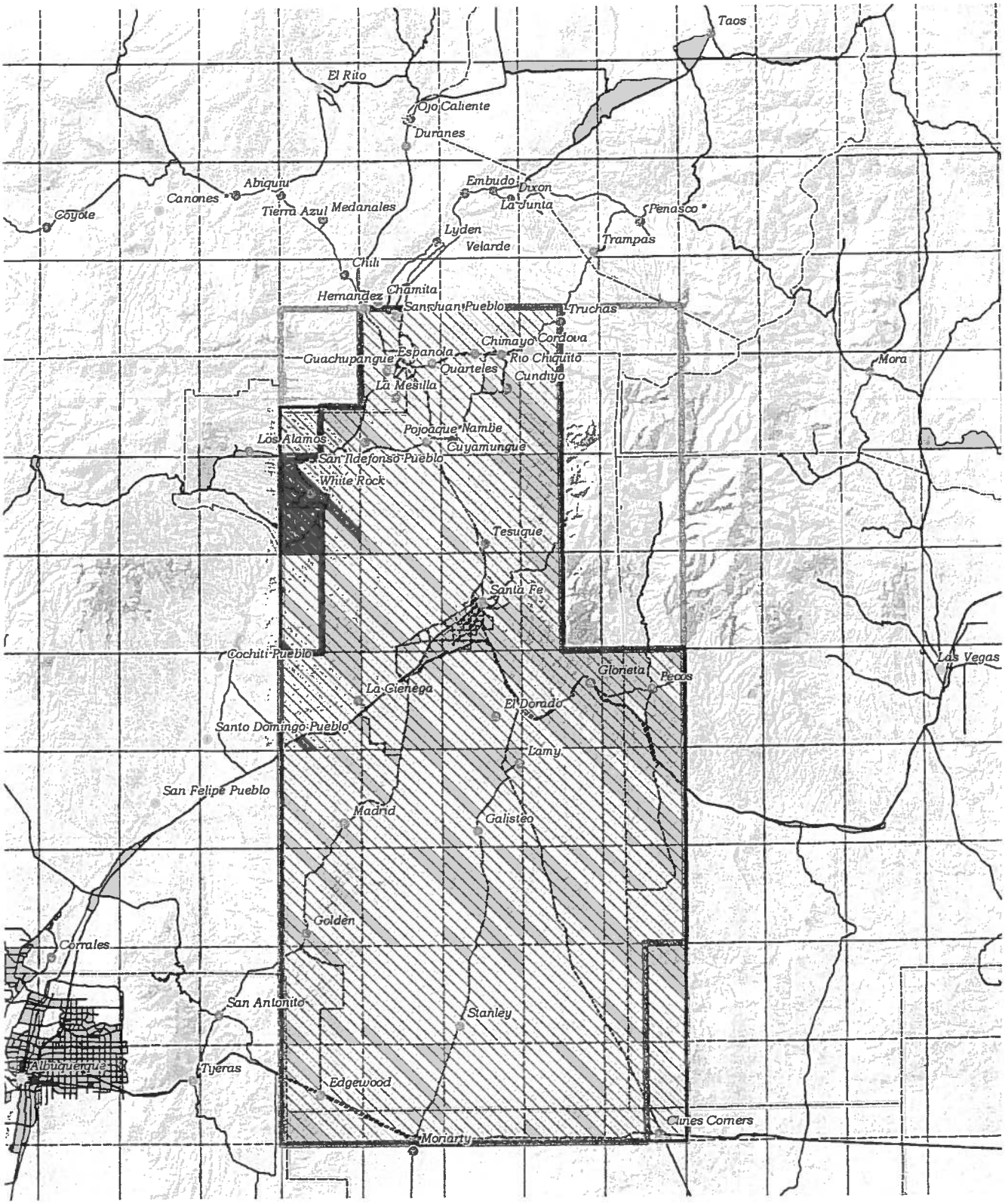
1:710,723
1 inch represents 11.22 miles
North American Vertical Datum 1988
4 2 0 4 8 12 16
Miles

SANTA FE COUNTY

N

January 31, 2014

Exhibit B - Proposed Ortho Photo Project Area



Legend

- Digital Imagery Acquisition Area
- Ortho Photo Production Area
- Minimum LiDAR Project Area
- County Boundaries
- 7.5" USGS Quad Lines
- Roads

1:710,723
1 inch represents 11.22 miles
North American Vertical Datum 1988
4 2 0 4 8 12 16
Miles

N

January 31, 2014

GSD/PD (Rev. 01/11)

State of New Mexico
General Services Department
Purchasing Division

Statewide Price Agreement Amendment

Awarded Vendor
0000046346
Bohannon Huston
7500 Jefferson NE, Courtyard 1
Albuquerque, NM 87109

Telephone No. (505) 823-1000

Price Agreement Number: **10-000-00-00051 BS**

Price Agreement Amendment No.: **THREE**

Term: **July 1, 2011 – March 31, 2015**

Ship To:
All State of New Mexico agencies, commissions, institutions, political subdivisions and local public bodies allowed by law.

Invoice:
As Requested

Procurement Specialist: Teri Arevalo TA

Telephone No.: (505) 827-0266

Title: **IT Professional Services**

This Price Agreement Amendment is to be attached to the respective Price Agreement and become a part thereof.

In accordance with Price Agreement provisions and by mutual agreement of all parties, this Price Agreement is extended from March 30, 2014 to March 31, 2015, at the same price, terms and conditions.

The provisions of the Price Agreement shall remain in full force and effect, except as modified by this amendment.

Accepted for the State of New Mexico

Paul Kyncl

New Mexico State Purchasing Agent

Date: 2/3/14

GSD/PD (Rev. 01/11)

State of New Mexico
General Services Department
Purchasing Division

Statewide Price Agreement Amendment

Awarded Vendor **0000046346** **Bohannon Huston** **7500 Jefferson NE, Courtyard 1** **Albuquerque, NM 87109** **Telephone No. (505) 823-1000**

Price Agreement Number: **10-000-00-00051BS**

Price Agreement Amendment No.: **Two**

Term: **July 1, 2011 – March 30, 2014**

Ship To: **All State of New Mexico agencies, commissions, institutions, political subdivisions and local public bodies allowed by law.**
Invoice: **As Requested**

Procurement Specialist: India Garcia

Telephone No.: (505) 827-0483

Title: **IT Professional Services**

This Price Agreement Amendment is to be attached to the respective Price Agreement and become a part thereof.

In accordance with Price Agreement provisions, and by mutual agreement of all parties, this Price Agreement is extended from June 1, 2013 to March 30, 2014 at the same price, terms and conditions.

Except as modified by this amendment, the provisions of the Price Agreement shall remain in full force and effect.

Accepted for the State of New Mexico

New Mexico State Purchasing Agent

Date: 2/18/13

Purchasing Division, 1100 St. Francis Drive 87505, PO Box 6850, Santa Fe, NM 87502-6850 (505) 827-0472

AM

GSD/PD (Rev. 01/11)

State of New Mexico
General Services Department
Purchasing Division

Statewide Price Agreement Amendment

Awarded Vendor **0000046346** **Bohannon Huston** **7500 Jefferson NE, Courtyard 1** **Albuquerque, NM 87109** **Telephone No. (505) 823-1000**

Price Agreement Number: **10-000-00-00051BS**

Price Agreement Amendment No.: **One**

Term: **July 1, 2011 – May 31, 2013**

Ship To: **All State of New Mexico agencies, commissions, institutions, political subdivisions and local public bodies allowed by law.**
Invoice: **As Requested**

Procurement Specialist: Gerrie Becker

Telephone No.: (505) 476-3121

Title: **IT Professional Services**

This Price Agreement Amendment is to be attached to the respective Price Agreement and become a part thereof.

In accordance with Price Agreement provisions, and by mutual agreement of all parties, this Price Agreement is extended from March 31, 2012 to May 31, 2013 at the same price, terms and conditions.

Except as modified by this amendment, the provisions of the Price Agreement shall remain in full force and effect.

Accepted for the State of New Mexico

New Mexico State Purchasing Agent

Date: 01/17/12

AM

State of New Mexico
General Services Department

Statewide Price Agreement

Awarded Vendor
0000046346
Bohannon Huston
7500 Jefferson NE Courtyard 1
Albuquerque, NM 87109

Telephone No. 505-823-1000

Price Agreement Number: 10-000-00-00051BS

Payment Terms: Per Contract

F.O.B.: Per Contract

Delivery: Per Contract

Ship To:
All State of New Mexico agencies, commissions, institutions, political subdivisions and local public bodies allowed by law.

Invoice:
As Requested

Procurement Specialist: Gerrie Becker

Telephone No.: 505-476-3121

Title: **IT Professional Services**

Term: **July 1, 2011 thru March 30, 2012**

This Price Agreement is made subject to the "terms and conditions" shown on the reverse side of this page, and as indicated in this Price Agreement.

Accepted for the State of New Mexico

Sandra K. Lovato BR
New Mexico State Purchasing Agent

Date: 6/30/11

CM

State of New Mexico
Information Technology

Price Agreement

Price Agreement No. 10-000-00-00051BS

THIS Information Technology Price Agreement ("Agreement") is made by and between the State of New Mexico, State Purchasing Division, hereinafter referred to as the "Agency" and Bohannan Huston, Inc., hereinafter referred to as the "Contractor" and collectively referred to as the "Parties".

WHEREAS, pursuant to the Procurement Code, NMSA 1978 13-1-28 *et. seq*; and Procurement Code Regulations, NMAC 1.4.1 *et.seq*; the Contractor has held itself out as expert in implementing the Scope of Work as contained herein and the Agency has selected the Contractor as the Offeror most advantageous to the State of New Mexico; and

WHEREAS, all terms and conditions of this Agreement, the Contractor's proposal, including any best and final offers, and the RFP are hereby incorporated by reference in this contract. In the event of a conflict between these items, the conflict will be resolved by giving priority in the following order:

1. All federal and New Mexico laws, rules and regulations regarding services within the Contractor's scope of work.
2. This Agreement and any written amendments to this Agreement.
3. The Request for Proposal (RFP), all RFP amendments, written clarifications to the RFP, and written answers to written questions concerning the RFP.
4. Contractor's Best and Final Offer
5. Contractor's Proposal.

ARTICLE 1 – DEFINITIONS

A. "Acceptance" shall mean the approval, after Quality Assurance, of all Deliverables by an executive level representative ("Executive Level Representative") of the Agency.

B. "Change Request" shall mean the document utilized to request changes or revisions in the Scope of Work.

C. "Chief Information Officer ("CIO")" shall mean the Secretary of the Department of Information Technology for the State of New Mexico or designated representative.

D. "Deliverable" shall mean any verifiable outcome, result, service or product that must be delivered, developed, performed or produced by the Contractor as defined by the Scope of Work.

E. "DoIT" shall mean the Department of Information Technology.

F. "DFA" shall mean the Department of Finance and Administration; "DFA/CRB" shall mean the Department of Finance and Administration, Contracts Review Bureau.

G. "Escrow" shall mean a legal document (such as the software source code) delivered by the contractor into the hands of a third party, to beheld by that party until the performance of a condition is accepted; in the event contractor fails to perform, the grantee agency receives the legal document, in this case, source code.

H. "Enhancement" means any modification or addition that, when made or added to the program, materially changes its or their utility, efficiency, functional capability, or application, but does not constitute solely an Error Correction. After conferring with Agency, an Enhancement may be identified as minor or major.

I. "Know How" shall mean all technical information, data and knowledge including, but not limited to, all documents, computer storage devices, drawings, flow charts, plans, proposals, records, notes, memoranda, manuals and other tangible items containing, relating or causing the enablement of any Intellectual Property developed under this Agreement.

J. "Intellectual Property" shall mean any and all proprietary information developed pursuant to the terms of this Agreement.

K. "Independent Verification and Validation ("IV&V")" shall mean the process of evaluating a project and the project's product to determine compliance with specified requirements and the process of determining whether the products of a given development phase fulfill the requirements established during the previous stage, both of which are performed by an entity independent of the Agency.

L. "Payment Invoice" shall mean a detailed, certified and written request for payment of services rendered from the Contractor to the Agency. Payment Invoice(s) must contain the fixed price Deliverable cost and identify the Deliverable for which the invoice is submitted.

M. "Performance Bond" shall mean a surety bond which guarantees that the contractor will fully perform the contract and guarantees against breach of contract.

N. "Project" shall mean a temporary process undertaken to solve a well-defined goal or objective with clearly defined start and end times, a set of clearly defined tasks, and a budget. The project terminates once the project scope is achieved and project approval is given by the Executive Level Representative and verified by the agency CIO to the DoIT.

O. "Project Manager" shall mean a qualified person from the Agency responsible for all aspects of the Project

P. "Quality Assurance" shall mean a planned and systematic pattern of all actions necessary to provide adequate confidence that a Deliverable conforms to established requirements, customer needs, and user expectations.

Q. "State Purchasing Agent (SPA)" - shall mean the State Purchasing Agent for the State of New Mexico or designated representative.

R. "State Purchasing Division (SPD)"- shall mean the State Purchasing Division of the General Services Department for the State of New Mexico

ARTICLE 2 – SCOPE OF WORK

A. Scope of Work. The Contractor shall provide information technology services to the Procuring Agency in accordance with the completed IT Professional Services Contract and the terms and conditions of the price agreement at the rate shown in Exhibit A.

B. Performance Measures. In addition, each IT Professional Services Contract will become a part of the agreement. In the event of any conflict among these documents, the following order of precedence shall apply:

1) The terms and conditions of this document;
2) The completed Contract/Purchase Order;
3) The request for proposals document; and
4) The contractor's written proposal including the Best and Final Offer, if one was submitted.

C. This is not an exclusive Price Agreement. Procuring Agencies may obtain services from other sources during the Price Agreement term. The SPA makes no expressed or implied warranties whatsoever that any particular number of Purchase Orders will be issued or that any particular quantity or dollar amount of services will be procured.

ARTICLE 3 - COMPENSATION

All payments under this Price Agreement are subject to the following provisions:

a. Acceptance - In accordance with Section 13~1-158 NMSA 1978, Project Manager shall determine if the services provided meet Purchase Order specifications contained therein. No payment shall be made for any service until the services have been accepted in writing by the Project Manager. Unless otherwise agreed upon between Procuring Agency and the Contractor, within fifteen (15) days from the date the Project Manager receives written notice (Contractor's Invoice) from the Contractor that payment is requested for services, the Project Manager shall issue a written certification to the Contractor of complete or partial acceptance or rejection of the services.

b. Rejection - Unless the Executive Level Representative gives notice of rejection within the fifteen (15) day business day Acceptance period, the Deliverable will be deemed to have been accepted. If the Deliverable is deemed unacceptable under Quality Assurance, fifteen (15) days from the date the Executive Level Representative receives the Deliverable(s) and accompanying Payment Invoice, the Executive Level Representative will send a consolidated set of comments indicating issues, unacceptable items, and/or requested revisions accompanying the rejection. Upon rejection and receipt of comments, the Contractor will have ten (10) business days to resubmit the Deliverable to the Executive Level Representative with all appropriate corrections or modifications made and/or addressed. The Executive Level Representative will again determine whether the Deliverable(s) is Acceptable under Quality Assurance and provide a written determination within fifteen (15) business days of receipt of the revised or amended Deliverable. If the Deliverable is once again deemed unacceptable under Quality Assurance and thus rejected, the Contractor will be required to provide a remediation plan that shall include a timeline for corrective action acceptable to the Executive Level Representative. The Contractor shall also be subject to all damages and remedies attributable to the late delivery of the Deliverable under the terms of this Agreement and available at law or equity. In the event that a Deliverable must be resubmitted more than twice for Acceptance, the Contractor shall be deemed as in breach of this Agreement. The

Agency may seek any and all damages and remedies available under the terms of this Agreement and available at law or equity. Additionally, the Agency may terminate this Agreement.

c. Compensation - The approved maximum rates to be paid for services rendered are contained in the Services Schedule. The Procuring Agency may reimburse Contractor for reasonable travel/per diem expenses for work performed at distances greater than 100 miles from the Contractor's primary place of business in New Mexico. The conditions for travel, the type and amount expenses to be reimbursed shall be stated in the Procuring Agency Agreement. Travel time from the Contractor's primary place of business and the worksite is not billable.

d. Payment of Invoice - Payment will be made to the Contractor's designated mailing address.

e. Payment of Taxes - The Contractor shall be reimbursed by the Procuring Agency for applicable New Mexico gross receipts taxes or local option taxes for services rendered. Such taxes must be itemized separately on the invoice.

The payment of taxes for any money received under this Price Agreement shall be the Contractor's sole responsibility and shall be reported under the Contractor's Federal and State tax identification number(s).

f. Invoices - Invoices shall be submitted to the Project Manager.

g. Facilities and Equipment - The Procuring Agency shall provide contractor personnel with reasonable office work space and facilities including access to a local telephone service, copy machine usage and office supplies. Unless otherwise stated in the Procuring Agency Agreement, the contractor shall provide contractor personnel with any required personal computer equipment and software and shall reimburse the procuring agencies for all long distance telephone calls charged to the Procuring Agency.

h. Appropriations - The terms of this Price Agreement and any Purchase Orders are contingent upon sufficient appropriations and authorization being made by the Legislature of New Mexico or other appropriate governing bodies for performance pursuant to this Price Agreement. Notwithstanding any language to the contrary in this Price Agreement or in any Purchase Order or other document, a Procuring Agency may terminate its obligation under a Purchase Order, or any extension thereof, if sufficient appropriations and authorization are not made by the Legislature or other appropriate governing body to pay amounts due. The Procuring Agency's decision as to whether sufficient appropriations are available shall be accepted by the Contractor and shall be final and binding. However, Procuring Agencies agree not to use insufficient appropriations as a means of terminating a Purchase Order in order to acquire functionally equivalent services from a third party.

i. Release - The Contractor, upon final payment of the amount due under a Purchase Order, releases the State of New Mexico, and its agencies and public employees, from all liabilities, claims and obligations whatsoever arising from or under this Price Agreement. The Contractor agrees not to purport to bind the State of New Mexico to any obligation not assumed herein by the State of New Mexico, unless the Contractor has express written authority to do so, and then only within the strict limits of that authority.

ARTICLE 4 – TERM

The initial term of this Price Agreement shall be March 31, 2011 or as soon as possible thereafter, through March 30, 2012.

The SPA may extend the initial term of the Price Agreement for three (3) additional one-year terms, or portions thereof, by giving the Contractor a written offer to renew the agreement at least thirty (30) days prior to the expiration of the then-current term. Service rates can change each year at the time of renewal if exercised, any proposed increase in the maximum rates for each authorized service shall not exceed the lower of the increase in the published Consumer Price Index (or other index approved by the Agreement Administrator) during the previous agreement term~ or the percentage increase in the Contractor's published consultant rates.

Except as noted elsewhere in this paragraph, the SPA expects all terms and conditions of this Price Agreement to apply to any option temps exercised. No changes to terms and conditions shall be effective unless reduced to written amendment in accordance with Paragraph 15 of this Price Agreement.

ARTICLE 5 – TERMINATION

This Agreement may be terminated as follows:

A. General. By either Party upon written notice to be delivered to the other party not less than thirty (30) business days prior to the intended date of termination.

C. Obligations and Waiver. By termination pursuant to this Article, neither party may nullify obligations already incurred for performance or failure to perform prior to the date of termination. THIS ARTICLE IS NOT EXCLUSIVE AND DOES NOT CONSTITUTE A WAIVER OF ANY OTHER LEGAL RIGHTS AND REMEDIES AFFORDED THE AGENCY AND THE STATE OF NEW MEXICO CAUSED BY THE CONTRACTOR'S DEFAULT OR BREACH OF THIS AGREEMENT.

ARTICLE 6 – TERMINATION MANAGEMENT

A. Contractor. In the event this Agreement is terminated for any reason, or upon expiration, and in addition to all other rights to property set forth in this Agreement, the Contractor shall:

1.) Transfer, deliver, and/or make readily available to the Agency property in which the Agency has a financial interest and any and all data, Know How, Intellectual Property, inventions or property of the Agency.
2.) Incur no further financial obligations for materials, services, or facilities under the Agreement without prior written approval of the Agency;
3.) Terminate all purchase orders or procurements and any subcontractors and cease all work, except as the Agency may direct, for orderly completion and transition;
4.) Take such action as the Agency may direct, for the protection and preservation of all property and all records related to and required by this Agreement;
5.) Agree that the Agency is not liable for any costs arising out of termination and that the Agency is liable only for costs of Deliverables Accepted prior to the termination of the Agreement;
6.) Cooperate fully in the closeout or transition of any activities to permit continuity in the administration of Agency programs;
7.) In the event that this Agreement is terminated due to the Contractor's course of performance, negligence or willful misconduct and that course of performance, negligence, or willful misconduct results in reductions in the Agency's receipt of program funds from any governmental agency, the Contractor shall remit to the Agency the full amount of the reduction.

8.) Should this Agreement terminate due to the Contractor's default, the Contractor shall reimburse the Agency for all costs arising from hiring new contractor/subcontractors at potentially higher rates and for other costs incurred.

9.) In the event this Agreement is terminated for any reason, or upon its expiration, the Contractor shall assist and cooperate with the Agency in the orderly and timely transfer of files, computer software, documentation, system turnover plan, Know How, Intellectual Property and other materials, whether provided by the Agency or created by the Contractor under this Agreement, to the Agency, including but not limited to, user manuals with complete documentation, functional technical descriptions of each program and data flow diagrams. At the request of the Project Manager, the Contractor shall provide to the Agency a copy of the most recent versions of all files, software, Know How, Intellectual Property and documentation, whether provided by the Agency or created by the Contractor under this Agreement.

B. Agency. In the event this Agreement is terminated for any reason, or upon expiration, and in addition to all other rights to property set forth in this Agreement, the Agency shall 1) Retain ownership of all work products and documentation created pursuant to this Agreement; and 2) Pay the Contractor all amounts due for services Accepted prior to the effective date of such termination or expiration.

ARTICLE 7 –INDEMNIFICATION

A. General. The Contractor shall defend, indemnify and hold harmless the Agency, the State of New Mexico and its employees from all actions, proceedings, claims, demands, costs, damages, attorneys' fees and all other liabilities and expenses of any kind from any source which may arise out of the performance of this Agreement, caused by the negligent act or failure to act of the Contractor, its officers, employees, servants, subcontractors or agents, or if caused by the actions of any client of the Contractor resulting in injury or damage to persons or property during the time when the Contractor or any officer, agent, employee, servant or subcontractor thereof has or is performing services pursuant to this Agreement. In the event that any action, suit or proceeding related to the services performed by the Contractor or any officer, agent, employee, servant or subcontractor under this Agreement is brought against the Contractor, the Contractor shall, as soon as practicable, but no later than two (2) days after it receives notice thereof, notify, by certified mail, the legal counsel of the Agency, and the Risk Management Division of the New Mexico General Services Department.

B. The indemnification obligation under this Agreement shall not be limited by the existence of any insurance policy or by any limitation on the amount or type of damages, compensation or benefits payable by or for Contractor or any subcontractor, and shall survive the termination of this Agreement. Money due or to become due to the Contractor under this Agreement may be retained by the Agency, as necessary, to satisfy any outstanding claim that the Agency may have against the Contractor.

ARTICLE 8 – INTELLECTUAL PROPERTY

A. Product of Services: Copyright. All materials developed or acquired by the Contractor under this Price Agreement shall become the property of the Procuring Agency. Nothing produced, in whole or in part, by the Contractor under this Price Agreement shall be the subject of an application for copyright by or on behalf of the Contractor. The original and one copy of all materials, work papers, design documents, or other documents produced by the Contractor shall be indexed and placed in appropriately labeled binders and delivered to the Project Manager at the conclusion of a Purchase Order.

ARTICLE 9 – INTELLECTUAL PROPERTY INDEMNIFICATION

A. Intellectual Property Indemnification. The Contractor shall defend, at its own expense, the Agency, the State of New Mexico and/or any other State of New Mexico body against any claim that any product or service provided under this Agreement infringes any patent, copyright or trademark, and shall pay all costs, damages and attorney's fees that may be awarded as a result of such claim. In addition, if any third party obtains a judgment against the Agency based upon Contractor's trade secret infringement relating to any product or services provided under this Agreement, the Contractor agrees to reimburse the Agency for all costs, attorneys' fees and the amount of the judgment. To qualify for such defense and/or payment, the Agency shall:

1.) Give the Contractor written notice, within forty-eight (48) hours, of its notification of any claim;
2.) Allow the Contractor to control the defense and settlement of the claim; and
3.) Cooperate with the Contractor, in a reasonable manner, to facilitate the defense or settlement of the claim.

B. Agency Rights. If any product or service becomes, or in the Contractor's opinion is likely to become, the subject of a claim of infringement, the Contractor shall, at its sole expense:

1.) Provide the Agency the right to continue using the product or service and fully indemnify the Agency against all claims that may arise out of the Agency's use of the product or service;
2.) Replace or modify the product or service so that it becomes non-infringing; or
3.) Accept the return of the product or service and refund an amount equal to the value of the returned product or service, less the unpaid portion of the purchase price and any other amounts, which are due to the Contractor. The Contractor's obligation will be void as to any product or service modified by the Agency to the extent such modification is the cause of the claim.

ARTICLE 10 - WARRANTIES

NA

ARTICLE 11 – CONTRACTOR PERSONNEL

A. Approval of Contractor Personnel

Personnel proposed in the Contractor's written proposal to the Procuring Agency are considered material to any work performed under this Price Agreement.

a. Once a Purchase Order has been issued, no changes of personnel will be made by the Contractor without prior written consent of the Procuring Agency. Replacement of any Contractor personnel, if approved, shall be with personnel of equal ability, experience and qualifications. The Contractor will be responsible for any expenses incurred in familiarizing the replacement personnel to insure their being productive to the project immediately upon receiving assignments. Approval of replacement personnel shall not be unreasonably withheld.

b. The Procuring Agency shall retain the right to request the removal of any of the Contractor's personnel at any time.

ARTICLE 12 – STATUS OF CONTRACTOR

A. Independent Contractor. The Contractor and its agents and employees are independent contractors performing professional services for the Agency and are not employees of the State of New Mexico. The Contractor and its agents and employees shall not accrue leave, retirement, insurance, bonding, use of state vehicles, or any other benefits afforded to employees of the State of New Mexico as a result of this Agreement. The Contractor acknowledges that all sums received hereunder are personally reportable by it for income tax purposes as self-employment or business income and are reportable for self-employment tax.

B. Subject of Proceedings. Contractor warrants that neither the Contractor nor any officer, stockholder, director or employee of the Contractor, is presently subject to any litigation or administrative proceeding before any court or administrative body which would have an adverse effect on the Contractor's ability to perform under this Agreement; nor, to the best knowledge of the Contractor, is any such litigation or proceeding presently threatened against it or any of its officers, stockholders, directors or employees. If any such proceeding is initiated or threatened during the term of this Agreement, the Contractor shall immediately disclose such fact to the Agency.

ARTICLE 13- CHANGE MANAGEMENT

A. Changes. Contractor may only make changes or revisions within the Scope of Work as defined by Article 2 and Exhibit A after receipt of written approval by the Executive Level Representative. Such change may only be made to Tasks or Sub-Task as defined in the Exhibit A. Under no circumstance shall such change affect the:

1) Deliverable requirements;
2) Compensation due under the terms of this Agreement; or
3) Due Date of any Deliverable.

B. Change Request Process. In the event that circumstances warrant a change to accomplish the Scope of Work as described above, a Change Request shall be submitted that meets the following criteria: 1) The Project Manager shall draft a written Change Request for Executive Level Representative review and approval to include: the name of the person requesting the change, a summary of the required change, the start date for the change, the reason and necessity for change, the urgency level for the change, the elements to be altered, the impact of the change, the staffing plan associated with the change, the impact on the schedule for implementing the change, the cost impact, the risk assessment and a recommended approach to the change, and 2) The Executive Level Representative shall provide a written decision on the Change Request to the Contractor within a maximum of ten (10) working days of receipt of the Change Request. All decisions made by the Executive Level Representative are final. Change requests, once approved, become a part of the contract and become binding as a part of the original contract.

ARTICLE 14 – DEFAULT/BREACH

In case of default and/or breach by the Contractor, for any reason whatsoever, the Agency and the State of New Mexico may procure the goods or services from another source and hold the Contractor responsible for any resulting excess costs and/or damages, including but not limited to, direct damages, indirect

damages, consequential damages, special damages and the Agency and the State of New Mexico may also seek all other remedies under the terms of this Agreement and under law or equity.

ARTICLE 15 – EQUITABLE REMEDIES

Contractor acknowledges that its failure to comply with any provision of this Agreement will cause the Agency irrevocable harm and that a remedy at law for such a failure would be an inadequate remedy for the Agency, and the Contractor consents to the Agency's obtaining from a court of competent jurisdiction, specific performance, or injunction, or any other equitable relief in order to enforce such compliance. Agency's rights to obtain equitable relief pursuant to this Agreement shall be in addition to, and not in lieu of, any other remedy that Agency may have under applicable law, including, but not limited to, monetary damages.

ARTICLE 16 - LIABILITY

Contractor shall be liable for damages arising out of injury to persons and/or damage to real or tangible personal property before or after Acceptance, delivery, installation and use of the equipment, either at the Contractor's site or the Agency's place of business, provided that the injury or damage was caused by the fault or negligence of the Contractor or defect of the equipment or installation. Contractor shall not be liable for damages arising out of, or caused by, alterations to the equipment (other than alterations performed or caused by Contractor's officers, employees or agents) made by the Agency or for losses occasioned by the Agency's fault or negligence. Nothing in this Agreement shall limit the Contractor's liability, if any, to third parties and employees of the Agency or the State of New Mexico, or any remedy that may exist under law or equity in the event a defect in the manufacture of the equipment, or the negligent acts or omissions of the Contractor, its officers, employees, or agents, is the cause of injury to such person.

ARTICLE 17 – ASSIGNMENT

The Contractor shall not assign or transfer any interest in this Agreement or assign any claims for money due or to become due under this Agreement without the prior written approval of this Agreement's approval authorities.

ARTICLE 18 – SUBCONTRACTING

The Contractor shall not subcontract any portion of this Agreement without the prior written approval of the Agency. No such subcontracting shall relieve the Contractor from its obligations and liabilities under this Agreement, nor shall any subcontracting obligate payment from the Agency.

ARTICLE 19 – RELEASE

The Contractor's acceptance of final payment of the amount due under this Agreement shall operate as a release of the Agency, its officers and employees, and the State of New Mexico from all liabilities, claims and obligations whatsoever arising from or under this Agreement. The Contractor agrees not to purport to bind the State of New Mexico unless the Contractor has express written authority to do so, and then only within the strict limits of that authority.

ARTICLE 20 – CONFIDENTIALITY

Any confidential information provided to the contractor by the agency or, developed by the Contractor based on information provided by the agency in the performance of this Agreement shall be kept confidential and shall not be made available to any individual or organization by the Contractor without the prior written approval of the Agency. Upon termination of this Agreement, Contractor shall deliver all confidential material in its possession to the Agency within thirty (30) business days of such termination. Contractor acknowledges that failure to deliver such confidential information to the Agency will result in direct, special and incidental damages.

ARTICLE 21 –CONFLICT OF INTEREST

The Contractor warrants that it presently has no interest and shall not acquire any interest, direct or indirect, which would conflict in any manner or degree with the performance or services required under the Agreement. The Contractor certifies that the requirements of the Governmental Conduct Act, Sections 10-16-1 through 10-16-18, NMSA 1978, regarding contracting with a public officer, state employee or former state employee have been followed.

ARTICLE 22 - RECORDS AND AUDIT

The Contractor shall maintain detailed time and expenditure records that indicate the date, time, nature and cost of services rendered during this Agreement's term and effect and retain them for a period of three (3) years from the date of final payment under this Agreement. The records shall be subject to inspection by the Agency, CIO, SPA, and DFA. The Agency shall have the right to audit billings both before and after payment. Payment for services under this Agreement shall not foreclose the right of the Agency to recover excessive or illegal payments.

ARTICLE 23 - AMENDMENT

This Agreement shall not be altered, changed, or amended except by an instrument in writing executed by the Parties hereto. No amendment shall be effective or binding unless approved by all of the approval authorities.

ARTICLE 24 – NEW MEXICO EMPLOYEES HEALTH COVERAGE

A. If Contractor has, or grows to, six (6) or more employees who work, or who are expected to work, an average of at least 20 hours per week over a six (6) month period during the term of the contract, Contractor certifies, by signing this agreement, to:

(1) have in place, and agree to maintain for the term of the contract, health insurance for those employees and offer that health insurance to those employees no later than July 1, 2008 if the expected annual value in the aggregate of any and all contracts between Contractor and the State exceed one million dollars or;

(2) have in place, and agree to maintain for the term of the contract, health insurance for those employees and offer that health insurance to those employees no later than July 1, 2009 if the expected annual value in the aggregate of any and all contracts between Contractor and the State exceed $500,000 dollars or;

(3) have in place, and agree to maintain for the term of the contract, health insurance for those employees and offer that health insurance to those employees no later than July 1, 2010 if the expected annual value in the aggregate of any and all contracts between Contractor and the State exceed $250,000 dollars.

B. Contractor agrees to maintain a record of the number of employees who have (a) accepted health insurance; (b) declined health insurance due to other health insurance coverage already in place; or (c) declined health insurance for other reasons. These records are subject to review and audit by a representative of the state.

C. Contractor agrees to advise all employees of the availability of State publicly financed health care coverage programs by providing each employee with, as a minimum, the following web site link to additional information: http://insurenewmexico.state.nm.us/.

D. For Indefinite Quantity, Indefinite Delivery contracts (price agreements without specific limitations on quantity and providing for an indeterminate number of orders to be placed against it); Contractor agrees these requirements shall apply the first day of the second month after the offeror reports combined sales (from state and, if applicable, from local public bodies if from a state price agreement) of $250,000, $500,000 or $1,000,000, depending on the dollar value threshold in effect at that time.

ARTICLE 25 - MERGER, SCOPE, ORDER OF PRECEDENCE

A. Severable. The provisions of this Agreement are severable, and if for any reason, a clause, sentence or paragraph of this Agreement is determined to be invalid by a court or agency or commission having jurisdiction over the subject matter hereof, such invalidity shall not affect other provisions of this Agreement, which can be given effect without the invalid provision.

B. Merger/Scope/Order. This Agreement incorporates any and all agreements, covenants and understandings between the Parties concerning the subject matter hereof, and all such agreements, covenants and understanding have been merged into this Agreement. No prior agreement or understanding, verbal or otherwise, of the Parties or their agents or assignees shall be valid or enforceable unless embodied in this Agreement.

ARTICLE 26 – NOTIFICATION

Either party may give written notice to the other party in accordance with the terms of this paragraph. Any written notice required or permitted to be given hereunder shall he deemed to have been given on the date of delivery if delivered by personal service or hand delivery, or three (3) business days after being mailed.

To SPA: State Purchasing Agent
Purchasing Division
Joseph M. Montoya State Building, Room 2016

1100 St. Francis Drive
Santa Fe, New Mexico 87505

To Contractor: Bohannan Huston, Inc.
7500 Jefferson Street NE
Albuquerque, NM 87109

Either party may change its representative or address above by written notice to the other in accordance with the terms of this Paragraph 26. The carrier for mail delivery and notices shall be the agent of the sender.

ARTICLE 27– GENERAL PROVISIONS

A. Civil and Criminal Penalties. The Procurement Code, Sections 13-1-28 through 13-1-199 NMSA 1978, imposes civil and criminal penalties for its violation. In addition, the New Mexico criminal statutes impose felony penalties for illegal bribes, gratuities and kickbacks.

B. Equal Opportunity Compliance. The Contractor agrees to abide by all federal and state laws and rules and regulations, and executive orders of the Governor of the State of New Mexico, pertaining to equal employment opportunity. In accordance with all such laws of the State of New Mexico, the Contractor agrees to assure that no person in the United States shall, on the grounds of race, religion, color, national origin, ancestry, sex, age, physical or mental handicap, serious medical condition, spousal affiliation, sexual orientation or gender identity, be excluded from employment with or participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity performed under this Agreement. If Contractor is found not to be in compliance with these requirements during the life of this Agreement, Contractor agrees to take appropriate steps to correct these deficiencies.

C. Workers Compensation. The Contractor agrees to comply with state laws and rules applicable to workers compensation benefits for its employees. If the Contractor fails to comply with the Workers Compensation Act and applicable rules when required to do so, this Agreement may be terminated by the Agency.

D. Applicable Law. The laws of the State of New Mexico shall govern this Agreement. Venue shall be proper only in a New Mexico court of competent jurisdiction in the county where the Agency's main office is located. By execution of this Agreement, Contractor acknowledges and agrees to the jurisdiction of the courts of the State of New Mexico over any and all such lawsuits.

E. Waiver. A party's failure to require strict performance of any provision of this Agreement shall not waive or diminish that party's right thereafter to demand strict compliance with that or any other provision. No waiver by a party of any of its rights under this Agreement shall be effective unless expressed and in writing, and no effective waiver by a party of any of its rights shall be effective to waive any other rights.

F. Headings. Any and all headings herein are inserted only for convenience and ease of reference and are not to be considered in the construction or interpretation of any provision of this Agreement. Numbered or lettered provisions, sections and subsections contained herein, refer only to provisions, sections and subsections of this Agreement unless otherwise expressly stated.

G. Work Site. Work shall be performed at the Procuring Agency's site unless specified otherwise in the Procuring Agency Agreement.

H. Succession. This Price Agreement shall extend to and be binding upon the successors and assigns of the parties.

ARTICLE 28 - SURVIVAL

The Articles entitled Intellectual Property, Intellectual Property Ownership, Confidentiality, and Warranties shall survive the expiration or termination of this Agreement. Software License and Software Escrow agreements and other unexpired agreements entered into in conjunction with this Agreement shall survive the expiration or termination of this Agreement.

ARTICLE 29 – TIME

Calculation of Time. Any time period herein calculated by reference to "days" means calendar days; provided, however, that if the last day for a given act falls on a Saturday, Sunday, or a holiday as observed by the State of New Mexico, the day for such act shall be the first day following that is not a Saturday, Sunday, or such observed holiday.

ARTICLE 30- AGREEMENT ADMINISTRATOR

The SPA shall appoint an agreement administrator whose duties shall include, but not be limited to, the following:

a. The agreement administrator shall attempt to facilitate dispute resolution between the Contractor and procuring agencies. Unresolved disputes shall be presented to the SPA for resolution.

b. The agreement administrator shall review and recommend approval or disapproval of all requested changes to the Contractor's Services Schedule.

c. The agreement administrator shall advise the SPA regarding the Contractor's performance under the terms and conditions of the agreement.

d. The agreement administrator shall assist procuring agencies with the preparation of purchase orders and the approval thereof.

e. The agreement administrator shall review and accept quarterly utilization reports.

ARTICLE 31 – ADMINISTRATIVE REPORTING FEES

a. The contractor agrees to provide periodic price agreement utilization reports to the agreement administrator in accordance with the following schedule:

Period End	Report Due
June 30	July 31

September 30	October 31
December 31	January 31
March 31	April 30

b. The periodic report shall include the gross revenues for the period subtotaled by Procuring Agency name. If no revenue was generated for the period, a report shall be filed stating that fact. Reports containing revenue shall be accompanied with a check payable to SPA for an amount equal to one-half of one percent (0.0050) of the gross revenue for the period.

c. The failure to file the utilization reports and fees on a timely basis shall constitute grounds for suspension of the Price Agreement or termination of the Price Agreement for cause.

ARTICLE 32 – EMPLOYEE PAY EQUITY REPORTING

"Contractor agrees if it has ten (10) or more employees OR eight (8) or more employees in the same job classification, at any time during the term of this contract, to complete and submit the required reporting form (PE10-249 or PE250, depending on their size at the time) either within thirty (30) calendar days of contract award (if the contract did not result from a solicitation) or on the annual anniversary of the initial report submittal for contracts up to one (1) year in duration (if the contract did result from a solicitation).

"For contracts that extend beyond one (1) calendar year, or are extended beyond one (1) calendar year, contractor also agrees to complete and submit the required form-annually within thirty (30) calendar days of the annual contract anniversary date of the initial submittal date and, if more than 180 calendar days has elapsed since submittal of the last report, at the completion of the contract.

"Should contractor not meet the size requirement for reporting at contract award but subsequently grows such that they meet or exceed the size requirement for reporting, contractor agrees to provide the required report within ninety (90) calendar days of meeting or exceeding the size requirement. That submittal date shall serve as the basis for submittals required thereafter.

"Contractor also agrees to levy these reporting requirements on any subcontractor(s) performing more than 10% of the dollar value of this contract if said subcontractor(s) meets, or grows to meet, the stated employee size thresholds during the term of the contract. Contractor further agrees that, should one or more subcontractor not meet the size requirement for reporting at contract award but subsequently grows such that they meet or exceed the size requirement for reporting, contractor will submit the required report, for each such subcontractor, within ninety (90) calendar days of that subcontractor meeting or exceeding the size requirement. Subsequent report submittals, on behalf of each such subcontractor, shall be due on the annual anniversary of the initial report submittal. Contractor shall submit the required form(s) to the State Purchasing Division of the General Services Department, and other departments as may be determined, on behalf of the applicable subcontractor(s) in accordance with the schedule contained in this paragraph. Contractor acknowledges that this subcontractor requirement applies even though contractor itself may not meet the size requirement for reporting and be required to report itself.

"Contractor shall not be required to report more frequently than annually unless more than 180 calendar days has elapsed since submittal of the last report and the contract has reached completion. The requirement for reporting at contract completion shall not apply in the case of a one-time fulfillment of a purchase order."

ARTICLE 33 – FORCE MAJEURE

Neither party shall be liable in damages or have any right to terminate this Agreement for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its control including, but not limited to Acts of God, Government restrictions (including the denial or cancellation of any export or other necessary license), wars, insurrections and/or any other cause beyond the reasonable control of the party who performance is affected.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date of the signature by the required approval authorities below.

By: _____ Date: June 14, 2011
Dennis Sandin, Senior Vice President
Bohannan Huston, Inc.

By: _____ Date: 6/27/11
Jay R. Hone, GSD General Council
For Legal Sufficiency

The records of the Taxation and Revenue Department reflect that the Contractor is registered with the Taxation and Revenue Department of the State of New Mexico to pay gross receipts and compensating taxes:

CRS ID Number: 01-503914-005

By: _____ Date: 6/28/11
Taxation & Revenue Department

Approved as to information technology contractual specifications and compliance with the Department of Information Technology Act, Laws 2007, Chapter 290 and any and all Executive Orders relating to Information Technology issued by the Governor of the State of New Mexico:

By: _____ Date: 6/30/11
Darryl Ackley, Secretary
Department of Information Technology

This Agreement has been approved by the SPA:

By: _____ Date: 6/30/11
Purchasing Agent for the State of New Mexico

Exhibit A

Service Category 6 Geographical Information System Services

Sub-service Category	Skills	Maximum Hourly Service Rate	Training Rate (Optional)	Products Supported
Geographic Information System Services	GIS-PA1	$83.73	NA	ESRI GIS Products, Intergraph GIS, Open Source GIS Products
	GIS-PA2	$143.71	NA	
	GIS-PA3	$174.54	NA	

NO PACKET MATERIAL FOR THIS ITEM

NO PACKET MATERIAL FOR THIS ITEM

Date: February 10, 2013

To: Board of County Commissioners

From: Adair Waldenberg, Chair
Santa Fe County Ethics Board

Subject: Quarterly Santa Fe County Ethics Board Report

Ethics Complaints Brought to the Board

No ethics complaints were brought to the Board during the past quarter.

Review of Ethics Training, Policies and Procedures

The Board has spent its time reviewing, discussing and considering possible proposed amendments to the Code of Conduct Ordinance. The changes will clarify and strengthen the existing ordinance. We will bring forward these proposed amendments at the February 25th Board of County Commission Meeting for consideration of Advertising Title and General Summary for two public hearings March 25 and April 29 for a vote on April 29th . You will have our proposed changes well in advance of the first meeting.

The County staff members have contributed their ideas and feedback to the Board, and we acknowledge and express our gratitude for their efforts.

If you have any questions or comments about these activities of the Santa Fe County Ethics Board, please contact me.

Adair L. Waldenberg
Chair
Santa Fe County Ethics Board
adair@northwestern.edu
505-983-1955

Attachments
Proposed Amendments to the Code of Conduct Ordinance

NO PACKET MATERIAL FOR THIS ITEM

NO PACKET MATERIAL FOR THIS ITEM

NO PACKET MATERIAL FOR THIS ITEM

EXECUTIVE SESSION

Date: February 12, 2014

To: Board of County Commissioners

From: Penny Ellis-Green, Growth Management Director

Via: Katherine Miller, County Manager

Re: Growth Management Monthly Report – January 2014

This report is a summary of projects for Growth management with statistics January 2014. Growth Management consists of 3 divisions; planning, GIS and Building and Development services.

Planning Division

Affordable Housing

Three requests for down payment assistance in the amount of $50,000 were approved in January. Two requests in the amount of $20,000 each were approved for two households, with both earning under 65% of Area Median Income. One household is a current public housing tenant, a single woman with two children. Another is an elderly single woman who will be buying her first home. The third recipient of assistance is a single man who teaches at a local Catholic school. The first two buyers are pursuing the purchase of existing homes originally built under the County inclusionary zoning program, and would be assuming substantial existing subsidy loans from the County, in addition to receiving the down payment assistance. The third buyer would be purchasing a home in La Entrada, which would be the first affordable home sold and closed since the execution of the amended and restated affordable housing agreement in December, 2012.

The Board of County Commissioners approved an amended and restated affordable housing agreement for Oshara Village. The agreement recognizes the change in ownership and brings the project under the umbrella of the 2006-02 Affordable Housing Ordinance, as amended by the 2012-1 Ordinance. This insures that this project will be treated equally with Rancho Viejo and La Pradera developers who received approval of similar amended and restated affordable housing agreements one year ago.

Open Space

Planning Division staff submitted a grant application to the Federal Lands Access Program for $1.87M for design and construction of El Camino Real de Tierra Adentro National Historic Trail (Buckman Road Segment) as authorized by the Board via Resolution 2013-141. The El Camino Real Buckman Road Retracement Project involves the development of a trail retracing a portion of El Camino Real along Old

Buckman Road (CR 77) and the creation of a multi-use trail along CR 62 and Caja del Rio Road linking this oldest segment of El Camino Real to the Santa Fe River Greenway.

Santa Fe County received seven applications from qualified individuals wishing to fill the three open positions on the County Open Lands and Trails Planning and Advisory Committee (COLTPAC). The Board of County Commissioners (BCC) made three appointments on Tuesday, January 28, 2014, at their Regular Meeting – Dave Dannenberg (District 4), Judy Kowalski (At-Large, re-appointment), and Patricia Conoway (At-Large).

Planning staff is coordinating with the Santa Fe River Traditional Communities Collaborative regarding collaborative management planning for the Santa Fe River corridor, particularly south of the waste water treatment plant to La Cienega and further to La Bajada.

Planning staff is coordinating with Glorieta Camps staff on a proposed trailhead and new trail connection to improve public access to the Glorieta Baldy Trails through the old Glorieta Baptist Center property.

Planning staff is preparing a scope of work for an Open Space, Trails and Parks Plan to ensure program goals and objectives are consistent with the SGMP and SLDC, update the facility inventory and set management priorities, and to strategically identify and prioritize projects for the CIP.

Community Planning
Chimayò Community Plan:
The planning effort is in its final phase. Current work is focused on refining strategies for implementation and identifying, analyzing and mapping appropriate land uses to achieve goals and objectives. Regular committee meetings to review information and discuss strategies and recommendations are on-going. County will be hosting two community open houses scheduled for Feb 12th and 15th.

In January planning staff:
- facilitated a half day work session with Rio Arriba planning staff
- attended meetings with the County Sheriff Department to discuss Crime Prevention
- prepared material for community open houses
- prepared and distributed material for community outreach

North Central Regional Transit District
The NCRTD Board approved a new service plan and will be presenting this to the BCC in February or March.

Economic Development
The Economic Development Manager, David Griscom, participated in an Outdoor Retailer Winter Trade Show in Salt Lake City. The Outdoor Recreation/EcoTourism is a target industry for SF County, as identified in the SGMP and the draft Economic Development Plan. The recruitment effort was a collaboration between SF County, City of Santa Fe, Regional Development Corporation, and NM Partnership. The NM Partnership organized and scheduled one-on-one meetings with approximately 25 companies and more leads were created via a Lead Retrieval system at the booth, with 29 additional companies and individuals identified who expressed interest in Santa Fe or NM in general. Most of the

companies and individuals we met with expressed interest in the business climate in Santa Fe, and all expressed interest in assistance in getting their respective products into local Santa Fe stores. The "Santa Fe" brand is well known, and most companies and individuals pointed to quality of life values with regards to considering the region for possible relocation. There are several "prospects" from the list of companies, and communications are ongoing. Follow up letters have been sent by the NM Partnership to those entities that visited the booth, and the County, City, and RDC are collaborating on sending out follow up letters to the remaining companies.

David also attended the Shoot Santa Fe event at the Sundance Film Festival on Jan. 20 as the SF County Film Liaison. This was a meet/greet lunch that was targeted to film/TV producers and directors from New Mexico as well as from around the United States. There were over 300 guests that attended. Shoot Santa Fe was one of the sponsors of the event, and there are 2 promising leads that have emerged as a result.

Food Policy Council
Planning staff participated in a facilitated all day Intercultural Competency Workshop training as a precursor to the community outreach meetings in the County for the draft Food Plan. Community Outreach meetings will be held in several areas of the County from March through June of this year to gain the communities perspective on food and farming in the County.

SLDC
The adopted SLDC was recorded and copies are currently being printed. The recorded version and a searchable version of the SLDC are on the County web page.

At this time the implementation schedule is as follows:

March 1-28, 2014	Prepare Public Notice Letters
March 21, 2014	Zoning Map Adoption Draft Released
March 31, 2014	Public Notice Letters Mailed
April 7 – 18, 2014	Public Review Period
April 29, 2014	BCC Regular Meeting, Request to Publish Title and General Summary of Technical Changes to the SLDC and release Technical Changes to the SLDC
May 6, 2014	Special Board of County Commission Meeting: 1st Public Hearing for Zoning Map 1st Public Hearing on Technical Changes to the SLDC
May 7-23, 2014	Draft Changes to Zoning Map and release Final Draft of Zoning Map
June 3, 2014	Special Board of County Commission Meeting: 2nd Public Hearing for Adoption of the Zoning Map 2nd Public Hearing for Adoption of Technical Changes to the SLDC
November 25, 2014	Board of County Commission 6 month Review

Building and Development Services Division

Permits and Development Review
The following statistics are provided for permits and approvals issued in January 2014:

	January 2014
New Residential Permits - Stick Built Homes	2
New Residential Permits - Mobile Homes	5
Commercial Building Permits	0
Number of Lots Created – Subdivision Exemptions	0 lots
Summary Review Subdivisions	0 lots
Subdivisions	0 lots
Commercial Business Licenses	0
Home Occupations Business licenses	3
Film Permits	1

Code Enforcement
The following statistics are provided for code enforcement actions in January 2014:

	January 2014
Number of Initial Notices of Violation Issued	23
Number of Final Notices of Violation Issued	5
Number of Notices of Violation resolved without court action	16

GIS Division

GIS is moving forward with the orthophotography and LiDAR (terrain) data contract. Staff has been reaching out to possible collaborators including USGS, Rio Arriba County, Española City, USFS, OSE, and others. Collaborators may help to increase the geographic coverage of the project, and reduce the per-unit cost (the per-square-mile cost) but not reduce our total dollar commitment. By expanding the geographic area we would get enough coverage of watershed boundaries to do hydrologic modeling over entire basins (e.g. Pojoaque basin, Galisteo basin) and do more accurate wildfire modeling and post-fire flood and rehabilitation impact assessments.

Nine courses were attended at NM EDGE by GIS staff in January. Debra Garcia received her Certified Public Official designation

In January the E911 Addressing staff replaced 79 addresses.

Pablo Sedillo, III
Public Safety Director

To: Santa Fe County Board of County Commissioners
From: Pablo Sedillo, III
Public Safety Department Director
Via: Katherine Miller
County Manager
Date: 2/12/14
Re: SFC Public Safety Department Monthly Report for January 2014

The purpose of this memo is to provide you information relative to the SFC Public Safety Department for the month of January 2014.

CORRECTIONS DEPARTMENT

Adult Detention Facility (ADF)

Administration

- The Adult Detention Facility was presented with a Certificate of Accreditation by New Mexico Association of Counties Detention Affiliates. Compliance Manager; Anthony Martinez, and CQI Coordinator; Ardis Thomas accepted the certificate on behalf of ADF in recognition of meeting professional standards of detention administration established by the Adult Detention Professional Standards Council.
- We received twelve (12) female inmates from the Metropolitan Detention Center (MDC) on Thursday, January 23, 2014. For the month of January Santa Fe County served a total of 53 inmates from MDC.
- Promoted Corporal Raymundo Lujan to Sergeant.
- Two employees participated in the NM Edge Courses.
- Detention Officer Testing was completed; 9 tested and 3 were hired.
- US Marshal's audit team conducted an unannounced audit which included auditing 205 Federal Jail Standards in which our Facility scored a 100% compliance score.

Programs

- Renee Fernandez, Programs Manager was transferred to the Youth Development Program to act as Interim Administrator
- Held a Volunteer Service Training for 42 volunteers.
- Recycling program was initiated on January 22, 2014 for the entire facility, which inmates will spearhead.
- Female Pod Bravo Unit Team began assisting the indigent inmates with envelopes and pens to write their families.
- Initiated a newsletter spearheaded by both staff and inmates, first issue should be issued in February.

Youth Development Program (YDP)

- Jemez living unit underwent extensive deep cleaning process, to include re-sealing of floors and painting of entire unit.
- Re-instated weekly Treatment Team Meetings.
- Increased therapeutic modalities, e.g., a "Theme of the Day" exercise are now in place. Staff and residents hold group for expectations in a.m., then process at noon and end of day.
- Interviews held for positions of Supervisor and Life Skill Worker's I and II.
- Student Nutrition Bureau – USDA conducted site inspection and audit of records. Exit review held, positive results were shared.

Electronic Monitoring (EM)

- There were 26 successful releases for January.
- Population has increased from 234 to 250 from December to January.

FIRE DEPARTMENT

Total emergency responses – 531
Fire – 136
EMS – 395

Operations and Administration

- Increased daily career staffing levels at Rancho Viejo from 2 to 4 personnel. This allows a quicker engine and ambulance response to emergency incidents and alleviates some of the call volume pressure on volunteer members.
- Completed the hiring process for 6 full time employees. Academy slated to start early March.
- Three (3) career personnel and three (3) volunteers are attending the Advanced Emergency Medical Technician (EMT) training program at the Santa Fe Community College (SFCC).
- Graduation ceremony for our 8th Volunteer Fire Academy (14 graduates) was held.
- Public Regulation Commission (PRC) inspection of ambulances and Emergency Medical Service (EMS) program completed; we passed with flying colors.
- Continued instructor/coordinator work at the Paramedic Training Academy, Albuquerque Fire Department, three (3) SFCFD students doing extremely well.
- Hired Senior Accounting Technician.
- Completed Mid-year budget review.
- Certificate of Occupancy received for La Cienega Fire Station remodel; office space for Fire Prevention and Wildland Divisions.
- Three capital projects underway: Pojoaque volunteer quarters remodel, Hondo Station 1 addition, and Glorieta substation.
- Received new wildland fire engine for Eldorado District.
- Contractor selected for remodel of La Cienega Station 2 remodel.
- Total ambulance revenue collected from July 1, 2013 through January, 31, 2014 is $372,416.

Fire Prevention and Wildland

- Business registrations – 8
- Development Reviews – 29
- Lot line Adjustments/Land Divisions/Family Transfers – 4
- School Presentations – 0
- School inspections – 10
- Burn Permits issues - 15

- 4 wildland classes taught reaching 48 volunteer members
- 43 home assessments conducted
- 7 community outreach meetings

Volunteer Recruitment and Retention

- New member applications approved - 3
- New member applications received year to date – 3
- Met with TV Stations NMCW and MY50 to discuss marketing campaign
- Regional and volunteer in service training – Cancer in the fire service
- Received 24 applications for Spring 2014 Volunteer Fire Academy
- Elected as President of East Mountain Interagency Fire Protection Association

Emergency Management

- Attended two week training course at the National Fire Academy – Natural and Man-Made Disaster Response
- Inventory, cleaning, and readiness to respond work done on cache of Emergency Management Equipment and apparatus.

RECC

Operations

- Incoming calls handled to date
  - January 2014 – 32,936
  - Calendar Year to Date – 32,936
- 911 calls to date
  - January 2014 – 5,196
  - Calendar Year to Date – 5,196
- County calls for service to date
  - January 2014 – 8,619
  - Calendar Year to Date – 8,619
- City calls for service to date
  - January 2014 – 13,513
  - Calendar Year to Date – 13,513
- Town of Edgewood calls for service to date
  - January 2014 – 548
  - Calendar Year to Date – 548

Staffing

- Current vacancies
  - 2 new hire Trainees waiting for HR approval
  - 2 Trainee positions still open
  - 2 new hire Call Takers waiting for HR approval
  - 1 Call Taker position still open
- Training Status
  - Two new Trainees are going through RECC Academy
  - One Trainee has completed the RECC Academy and is with a trainer on the floor
  - Four Trainees continue with their trainers at various stations
  - One Trainee has completed all stations and is working on the floor in full capacity

If you have any questions, I can be contacted at 992-3092. Thank you.

MEMORANDUM

DATE: *February 12, 2014*

TO: *Board of County Commissioners*

VIA: *Katherine Miller, County Manager*

FROM: *Adam Leigland, Public Works Director*

ITEM AND ISSUE: PUBLIC WORKS MONTHLY REPORT FOR FEBRUARY 2014

DISCUSSION

Capital Project Delivery

We are currently managing 66 procurements. Details on 28 of them follow below.

1. **Stanley Cyclone Center:** Contractor is to test well early next week on Phase 1. Staff conducted a meeting with the architect, Commissioner, Liaison staff, and other proponents of the project to confirm the programming requirements of the Phase II. The current schedule calls for bid opening to be at the end of May. Staff is investigating alternative procurement for the metal building to accelerate the construction schedule. The architect is preparing the first projection of construction costs so staff can evaluate the extent of any funding gaps that are anticipated.
2. **Madrid Oscar Huber Grandstands Phase 2:** Construction contract is scheduled to go to BCC for approval February 25, 2014. Notice To Proceed is anticipated to be given on March 3, 2014. The project should be completed by July 31, 2014.
3. **Oshara Play Equipment:** Playground to be complete by February 14, 2014.
4. **Cundiyo and El Rancho Playground Equipment:** Equipment is being procured for both playgrounds.
5. **La Bajada Ranch Main House:** Procurement is reviewing on-call bids for the remediation work.
6. **La Bajada Ranch Foreman's House:** Staff met with Architect to provide background on accessibility issues and public use. Pre-proposal meeting is scheduled for February 12th.

7. **Ken and Patty Adam Senior Center/County Community Center:** The Procurement Manager has determined it is best to rebid project due to several protests received. Project is schedule to advertise on February 23 and 24. Bids will open in mid-March with low bid scheduled to go in front of BCC on April 27, 2014.

8. **La Cienega Fire Station #2 Remodel:** Bids opened on January 23, 2014. Contract is scheduled to go in front of BCC approval on February 25, 2014. Construction is scheduled to begin March 10, 2014, with a 180-day performance period.

9. **La Cienega Fire Station #1 Renovation:** Communication lines installation is scheduled to be complete February 14. In-house forces scheduled to wax and seal new tile floors by February 14 as well. In-house team is also waiting on two new doors for installation and heater replacement in parts of the building outside the scope of the renovation.

10. **Glorieta Fire Station:** Surveyor began work. Scope of work will be finalized by February 14.

11. **Hondo Fire Station # 1 Remodel:** Design kick-off meeting held February 10.

12. **Greater Glorieta Waterline (CDBG):** Staff has completed the rebidding process for construction of the project and a contract for award will be presented to BCC on February 25. Construction could start as early as March 2014.

13. **Vista Redonda Subdivision Drainage and Road Improvements:** Notice to proceed for design given January 29. Preliminary drainage analysis completion anticipated by mid- to late March.

14. **Camino Torcido Loop:** Met with designer on February 6, 2014, to review scope of work for drainage study proposal which will include recommendations from drainage and road design. Proposal is scheduled to be submitted within the week of February 17, 2014.

15. **CR67F, La Barbaria Drainage and Road Improvement Project:** Completed design kick-off meeting on February 6, 2014.

16. **Valle Vista Force main Design:** Staff completed the 30% review for the design of the force main. Consultant is revising plans and will re-submit prior to proceeding beyond 30% stage.

17. **County Road 89 and 89C Drainage and Road Improvements:** Engineering design service contracts in procurement process.

18. **La Cienega Water Trust Board Pipeline Project:** Design awarded; kickoff meeting held February 12, 2014.

19. **Canoncito Waterline:** Negotiations for Rancho Viejo Easement are ongoing – will involve Growth Management, County Attorney's Office, Public Works/Utilities – development agreement is involved, which is projected to take up to three months. Accordingly easements should be secure by mid- to late April.

20. **Old Santa Fe Trail Waterline:** Design work wrapping up. Examining potential to move funding up to FY14/15 to complete project in tandem with Old Santa Fe Trail Multimodal Project.

21. **Las Lagunitas Wastewater Collection System:** Selection of design firm and financial analysis firms will took place on February 3. Notices to proceed issued February 14.

22. **Pojoaque Sports Fields:** Design kick-off meeting held February 4. Construction is scheduled to follow the Fall 2014 sport season at the request of the school.

23. **Rio Quemado Watershed Restoration:** Anticipate awarding the construction contract and beginning construction in early March.

24. **Santa Fe River Greenway Wayside Exhibits:** Notice to proceed issued February 14.

25. **Thornton Ranch Open Space:** Preparing BCC packet to award contract for cultural resource investigations at the February 25, 2014, BCC Meeting. Anticipate issuing notice to proceed for both contracts at the beginning of March. The cultural resource investigations and planning efforts are projected to take a year to complete.

26. **Agua Fria Monument Sign:** Construction contract in review. Construction is anticipated to begin in June 2014.

27. **Santa Fe Rail Trail:** Working on obtaining certifications from NMDOT for Segment 4. Anticipate obtaining project authorization in July 2014 and issuing IFB in August 2014.

28. **San Isidro Crossing Repairs**: Several of the new rock structures on the Santa Fe River below San Isidro Crossing were displaced after the 100-year storm event in September. Staff is working with Risk Management for funds to replace the structures under the guidance of Riverbend Engineering.

Information on all active projects can be found in the attached Table 1: Capital Project Status Update.

Operation and Maintenance

Work order completion rates for the month of January are shown at Table 2 (attached). The January overall completion rate was 89%.

The Solid Waste Task Force met on January 29, 2014, to review the solid waste study consultant's reports. After a presentation from the consultant, the Task Force felt that it was not ready to make any recommendations and requested an additional meeting. This meeting is scheduled for February 19, 2014.

Snow removal from the storm on February 3, 4 went very smoothly. Once again, County roads were cleared before City and State roads, and I personally received compliments on County snow removal from out-of-town attendees at a conference I was presenting at.

Staff are working to purchase and install a "beaver deceiver" for the two 24-inch culverts on Calle Debra Bridge. This is part of the larger effort to address the water retention issue caused by beaver dams on the Santa Fe River below the City's wastewater treatment plant. These deceivers fool the beavers into maintaining a lower level of water behind their dams.

A pipe burst in County's vacant building in Edgewood, the old fire station, which the Town of Edgewood wants to lease. The leak flooded approximately 80% of the office/living area. Remediation of the water damage and mold was completed expeditiously. To repair the damage will require a permit from the State Construction Industry Division (CID), who has stated that in order to receive the permit, the building's bathroom must be brought into ADA compliance. This is estimated to cost $3500 for repairing the water damage and $10,000 for the bathroom upgrade.

The County has entered into a volunteer arrangement with The Masters Program, an early college charter school, for open space maintenance. The first event was held on January 31, when 12 students and 1 instructor constructed fencing in San Isidro Park. This promises to be a great program over the next 10 weeks.

Utilities

The asset inspection and inventory for Hyde Park Estates Cooperative Water Association is about 50% complete with no major issues to report from the consultant. The system appears to be well run and in good condition. One easement issue relating to well no. 4 will need to be resolved as there is currently an unofficial agreement between the land owner and the water system.

The Chupadero MDWCA acquisition is also proceeding apace. Numerous easement issues are being ironed out now.

Finally, the asset inspection and inventory for Cañoncito at Apache Canyon MDWCA has just begun. The Chupadero and Canoncito systems share an attorney, so the hope is that lessons learned in the Chupadero process can be applied to the acquisition of Canoncito and save time and energy

ACTION REQUESTED:

None; for information only.

SANTA FE COUNTY

Capital Project Status Upd (As of 2/13/2014 4:50:14 PM)

	PW ProjectNbr	Project Name	Nature of Procurement	% Comp	District	Project Budget	Current Contract Amount	Estimated Start Date	Estimated Completion Date	Project Manager
1	0131	Construct Playground at Cundiyo and El Rancho Community Center	Construction	5	1	$70,000.00		3/3/2014	4/15/2014	David Padilla
2	0134	Preliminary Programming Study – Animal Control Facility	Design			$10,000.00		2/17/2014		
3	0135	Construct Playground Equipment in Oshara Village	Construction	95	5	$20,000.00	$20,000.00	2/3/2014	3/28/2014	David Padilla
4	0150	Public Safety Complex Upgrade Design	Design	10	1 2 3 4 5	$200,000.00		1/30/2014	7/31/2014	Paul Olafson
5	0732	Romero Park	Design	42	2	$175,000.00	$163,351.00	5/17/2013	3/31/2015	Colleen Baker
6	0736	Pojoaque Sports Fields	Design	10	1	$50,000.00	$83,169.00	1/28/2014	3/31/2015	Colleen Baker
7	0739	Vista Grande Library Addition / Construction	Construction	70	5	$1,050,000.00	$828,665.59	4/30/2013	3/15/2014	Ron Sandoval
8	0751	Oscar Huber Grandstand Phase II	Construction	5	3	$24,000.00	$22,719.38	2/5/2014	10/31/2014	David Padilla
9	0753	Construct Addition to Ken & Patty Adam Senior Center	Construction	3	5	$1,275,531.00		3/10/2014	1/30/2015	Ron Sandoval
10	0789	Cundiyo Parking Lot	Design	95	1	$8,557.63	$8,557.63	2/18/2013	5/16/2014	Chuck Vigil
11	0798	Design Old Santa Fe Trail Multimodial	Design	98	4	$264,692.00	$252,011.10	3/5/2013	3/28/2014	Chuck Vigil
12	0834	Design Hondo Fire Station #1 Addition	Design	7	4	$325,348.00		2/10/2014	5/30/2014	Ron Sandoval
13	0840	Remodel La Cienega Fire Station No. 1	Construction	98	5	$650,000.00	$541,230.88	6/30/2013	1/10/2014	Ron Sandoval
14	1449	Design Water Transmission Line TL6S	Design	45	4 5	$333,080.30	$333,080.30	2/17/2012	2/28/2014	Dennis Romero
15	1457	Design La Cienega Water Line Improvements	Design	29	3	$300,000.00		1/8/2014	4/30/2014	Dennis Romero
16	1463	Design Valle Vista Force Main	Design	35	3	$22,300.00	$22,300.00	7/15/2013	4/18/2014	Scott W. Rivers
17	1465	Construct Glorieta MDWCA Water System Improvements	Construction	27	4	$424,759.00		2/28/2014	5/1/2014	Dennis Romero
18	1472	Rio Quemado Watershed Restoration	Construction	57	1	$240,000.00	$96,681.75	5/8/2013	6/30/2014	Colleen Baker
19	1473	Quill Water Reclamation Plant – Treatment Improvements	Construction	10	5	$500,000.00		1/1/2014	10/31/2014	Dennis Romero
20	1473	Purchase and Install Quill Plant Utilities Offfice	Acquisition	15	1 2 3 4 5	$75,000.00		2/28/2014	4/28/2014	Scott W. Rivers
21	1474	Design Lamy Junction Water Transmission Line	Design	39	4 5	$411,368.96	$411,368.96	5/4/2012	6/5/2014	Dennis Romero
22	1474	Old Santa Fe Trail Water Line	Design	92	4	$190,000.00	$167,154.00	2/15/2013	1/31/2014	Dennis Romero
23	1476	Construct a Wastewater Collection and Water Reclamation System for Greater Glorieta	Construction		4	$600,000.00		1/1/2014	12/31/2014	Scott W. Rivers
24	1478	Design CR62/Caja del Oro Waterline Extension	Design	25	2	$212,636.00	$23,563.20	7/16/2013	3/28/2014	Scott W. Rivers
25	1860	Upgrade Perimiter & Interior Lighting at Adult Detention Facility, Upgrade Perimiter Lighting at Youth Development Program	Construction	20	1 2 3 4 5	$387,305.86	$335,875.00	1/20/2014	4/21/2014	Joseph Martinez

SANTA FE COUNTY

Capital Project Status Update (As of 2/13/2014 4:50:14 PM)

26	1870	Youth Development Center Perimeter Lighting	Construction	10	1 2 3 4 5	$200,000.00		8/5/2013	9/30/2013	Joseph Martinez
27	1870	Upgrade Security Cameras At Adult Dedention Facility, Upgrade Control Panel At Youth Development Program.	Construction	15	1 2 3 4 5	$310,000.00		2/3/2014	4/30/2014	Joseph Martinez
28	2219	Renovate Old Judicial Courthouse Redevelopment	Design	0	1 2 3 4 5	$475,000.00		6/2/2014	2/27/2015	Paul Olafson
29	4001	La Bajada Ranch Remediation and Reroofing	Construction	22	3	$70,000.00	$23,000.00	2/4/2014	4/3/2014	David Padilla
30	6167	CR 54 Los Pinos Road All Weather Structure Design	Design	60	3	$95,000.00	$79,411.76	8/12/2013	5/16/2014	Chuck Vigil
31	6170	CR98 Road Widiing Phase II - PR, Inspection and QA Services	Construction	99	1	$156,987.27	$159,287.79	9/16/2013	2/14/2014	Chuck Vigil
32	6181	NE-SE Connectors Location Study	Plan	47	5	$500,000.00	$420,000.00	2/4/2013	7/18/2014	Chuck Vigil
33	6182	CR 55A General Goowin Rd Design Upgrade	Design	30	3	$100,000.00	$30,357.55	9/23/2013	3/28/2014	Chuck Vigil
34	6183	Torcido Loop - Archaeological Survey	Archaeology	99	3	$48,683.69	$48,683.69	7/18/2013	3/14/2014	Chuck Vigil
35	6184	Herrada Road Paving Design	Design	85	5	$100,000.00	$86,474.16	8/12/2013	2/28/2014	Chuck Vigil
36	6196	Upgrade County Road 26 - Simmons Road	Construction	0	3	$460,000.00	$447,513.66	8/30/2013	9/16/2013	David Padilla
37	6197	Vista Rendonda Drainage and Road Paving Design	Design	15	1	$120,000.00	$90,590.78	12/16/2013	4/25/2014	Chuck Vigil
38	6198	Design drainage and Roadway improvements on County Road 89.	Design	5	1	$55,000.00		2/12/2014	6/30/2014	Scott W. Rivers
39	6199	Improvements on County Road 89 C	Design	5	1	$35,000.00		2/12/2014	6/30/2014	Scott W. Rivers
40	6202	Design drainage and roadway improvements on County Road 84 D	Design	5	1	$80,000.00		2/12/2014	6/30/2014	Chuck Vigil
41	6203	Design and construct drainage and pavement improvements for County Road 105	Design	5	1	$400,000.00		2/26/2014	9/30/2014	Chuck Vigil
42	6204	Design and construct drainage and pavement improvements for County Road 109 S	Design	5	1	$260,000.00		2/26/2014	9/30/2014	Chuck Vigil
43	6205	Construct Pavement improvements for bike lanes on County Road 89 D	Construction	5	1	$170,000.00		4/16/2014	8/1/2014	Chuck Vigil
44	6208	Public Works Programming & Master Plan	Plan	10	1 2 3 4 5	$25,000.00		2/28/2014	6/30/2014	Paul Olafson
45	6208	PW Phase 2 Sewer line construction	Construction	12	1,2,3,4,5	$81,429.00		3/10/2014	5/9/2014	Scott W. Rivers
46	7006	La Bajada Ranch Planning, Programming, & Design	Plan	10	3	$120,000.00		9/28/2012	3/29/2015	Mark Hogan
47	7120	Santa Fe River Greenway: Wayside Exhibit Planning, Design, Fabrication	Other	75	2	$84,841.50	$60,131.50	7/1/2012	9/30/2015	Colleen Baker
48	7121	Stanley Wellness Center Phase 1	Construction	42	3	$490,000.00	$188,963.00	5/7/2013	4/10/2014	David Padilla
49	7121	Design and Construct Stanley Community Wellness Center Phase 2	Design	10	3	$50,000.00		9/2/2013	2/14/2014	David Padilla
50	7122	Highway 14 Senior/Community Center	Acquisition	10	3	$350,000.00		11/5/2012	5/1/2014	Agnes Leyba-Cruz

51	7124	Admin Building Computer & Communications Room	Construction	0	1 2 3 4 5	$275,000.00		3/31/2014	7/31/2014	Paul Olafson
52	7701	Arroyo Hondo Trail	Design	19	5	$470,572.00	$442,524.00	12/13/2012	6/30/2014	Colleen Baker
53	7706	Mt. Chalchihuitl	Acquisition	25	3	$988,499.00	$52,859.35	8/1/2012	9/30/2014	Colleen Baker
54	7707	Santa Fe Rail Trail	Construction	7	4, 5	$1,578,212.00		7/1/2014	3/31/2015	Colleen Baker
55	7708	Santa Fe River Greenway Acquisition	Acquisition	15	2	$1,814,850.60	$531,756.83	10/9/2012	11/1/2014	Scott Kaseman
56	7708	Santa Fe River Greenway: Frenchy's Field to Siler Rd.	Archaeology	100	2	$59,406.47	$59,406.47	3/1/2009	12/31/2013	Scott Kaseman
57	7708	Santa Fe River Greenway Engineering Design Services	Design	76	2	$412,725.85	$333,601.57	10/3/2012	6/6/2014	Scott Kaseman
58	7711	Thornton Ranch Open Space	Plan	9	3	$200,000.00		3/3/2014	3/2/2015	Colleen Baker
59	7716	Construct South Meadows Open Space Phase 1	Construction		2	$400,361.00	$4,111.13	11/15/2013	5/12/2014	Scott W. Rivers
60	7723	Nambe Community Center, Park and Head Start Site Improvements	Construction	10	1	$349,079.00	$333,310.76	2/17/2014	6/30/2014	Colleen Baker
61	7725	Construct Playground Equipment at El Rancho Community Center	Construction	5	1	$45,000.00		3/3/2014	4/15/2014	David Padilla
62	7732	Agua Fria Monument Signs	Construction	8	2	$83,846.00		3/1/2014	6/30/2014	Colleen Baker
63	8008	La Cienega Fire Station No. 2 Apparatus bay expansion and Library remodel.	Construction	5	3	$494,091.00	$31,590.75	4/2/2014	9/30/2014	Ron Sandoval
64	8009	Glorieta Fire Station #2 - New Construction	Design	4	4	$50,000.00		2/10/2014	6/30/2014	Ron Sandoval
65	8010	Pojoaque Fire Station - Interior Remodel Volunteer Side	Design	3	1	$181,470.00		2/28/2014	6/27/2014	Ron Sandoval
66	9692	CR67F La Barbaria Drainage and Road Paving Design	Design	15	4	$100,000.00	$16,197.08	12/16/2013	4/25/2014	Chuck Vigil

Table 2: On-time k Order Completion
January 2013

Property Control

COMM. DIST.	REQUESTS	ISSUED	CLOSED	ON TIME
1	9	7	6	6
2	8	8	8	8
3	3	3	2	2
4	7	6	5	5
5	15	12	9	9
All	67	65	55	55
TOTAL	**109**	**101**	**85**	**85**
		93%	78%	78%

Building Services

COMM. DIST.	REQUESTS	ISSUED	CLOSED	ON TIME
1	2	0	0	0
2	5	5	5	5
3	1	1	1	1
4	1	1	1	1
5	1	1	1	1
All	13	12	12	12
TOTAL	**23**	**20**	**20**	**20**
		87%	87%	87%

Roads

COMM. DIST.	Overall WO's from public & staff	Overall WO Issued from public & staff	Overall WO Closed from public & staff	Request from public only	On-time request from public only
1	6	6	4	4	2
2	4	4	1	3	1
3	21	21	19	11	9
4	51	51	49	1	0
5	9	9	7	3	1
All	7	7	7	0	0
TOTAL	**98**	**98**	**87**	**22**	**13**
		100%	89%		59%

Open Space

COMM. DIST.	REQUESTS	ISSUED	CLOSED	ON TIME
1	28	28	28	28
2	17	16	16	16
3	12	12	12	12
4	6	6	6	6
5	8	8	8	8
All	25	25	25	25
TOTAL	**96**	**95**	**95**	**95**
		99%	99%	99%

Traffic

COMM. DIST.	Overall WO's from public & staff	Overall WO Issued from public & staff	Overall WO Closed from public & staff	Request from public only	On-time request from public only
1	34	34	30	0	0
2	6	6	6	0	0
3	11	11	11	2	2
4	9	9	9	0	0
5	7	7	7	4	4
All	6	6	4	0	0
TOTAL	**73**	**73**	**67**	**6**	**6**
		100%	92%		100%

MEMORANDUM

To: Board of County Commissioners

Via: Katherine Miller, County Manager
Bernadette Salazar, Human Resources Director

Date: February 12, 2014

Re: HR Monthly Report January 2014

Issue:

The HR Division provides the Santa Fe County Board of County Commission a monthly report regarding highlighted HR information and events.

Background:

The purpose of this memo is to provide you with information relative to various HR functions and statistics for the month of January 2014. Throughout the month January, HR coordinated/conducted sixteen training sessions. One-hundred seventy employees attended these training sessions. Also in January, Santa Fe County assisted thirty employees in attending New Mexico Edge courses. A total of ninety courses were taken. This resulted in assistance for a total of $4,250. During this session, five employees graduated with their New Mexico Certified Public Official Certification and one employee, Theresa Romero graduated with her New Mexico Certified Treasury Certification. Ms. Romero is the first employee from Santa Fe County to be awarded this certification. In addition, Santa Fe County assisted seven employees with tuition assistance for a total amount of $2,759.23 in January.

In regards to recruitment for the month of January, we conducted testing for the position of Detention Officer in which twenty people applied and nine attended the testing process. The new hire process for selected individuals is underway. Sergeant interviews were conducted and Mr. Raymundo Lujan was promoted. He has over hour years of service with Santa Fe County. The Sheriff's Office conducted Lieutenant testing and Gabriel Gonzales was promoted. He started his career as a Deputy Cadet with Santa Fe County over fourteen years ago. For the Fire Department, we recruited for the position of Firefighter EMT-Basic, Intermediate and Paramedic. We had thirty-five qualified applicants. Nineteen attended the testing process, and the new hire process is underway for the vacant positions.

In January, the HR Division attended the annual job fair for high school students from Santa Fe High School. This included outreach to students about careers with Santa Fe County, discussing what services the County provides, and explaining to them our hiring process. HR staff spoke to over one hundred students during the event. Thirty applications were taken by interested students. HR staff will be working with other high schools located in Santa Fe County to provide similar assistance to students. We believe this is a great way to educate our youth about what Santa Fe County has to offer.

Attached are the HR Statistics Report, the New Hire Report, and the Labor Statistics Report for January 2014. If you have any questions, I can be contacted at 992-9886. Thank you.

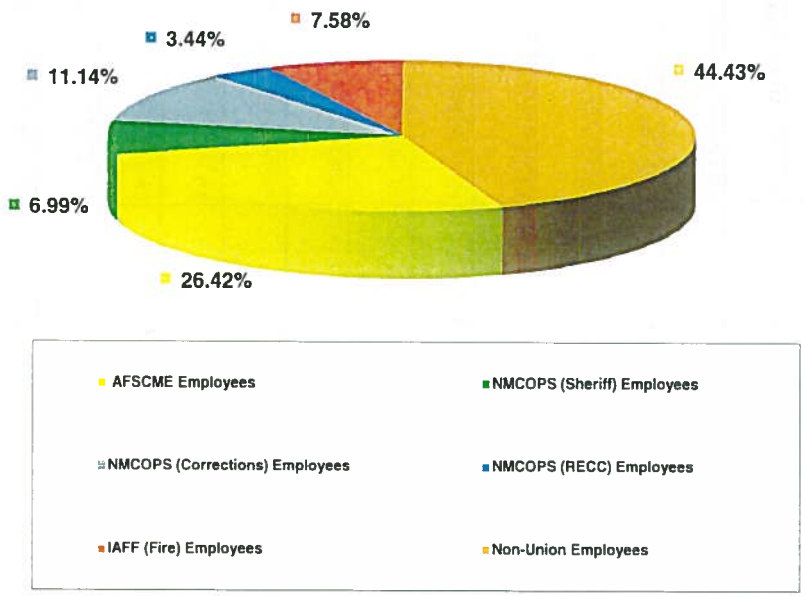
SANTA FE COUNTY NEW HIRE REPORT FOR JANUARY 1, 2014 - FEBRUARY 7, 2014

LAST NAME	FIRST NAME		DEPARTMENT	POSITION	EMP STATUS	HIRE DATE
GOMEZ	MICHAEL	A	ADMINISTRATIVE SERVICES DEPARTMENT	SYSTEMS ADMINISTRATOR	PB	1/13/2014
DELGADO	CHANELLE	G	COMMUNITY SERVICE DEPARTMENT	TEEN COURT COORDINATOR	PB	1/20/2014
ORTIZ DE HUERT	GRACIELA		COMMUNITY SERVICE DEPARTMENT	COOK	PB	1/6/2014
RINGKVIST	LEILANI	S	COMMUNITY SERVICE DEPARTMENT	SECRETARY SENIOR	PB	2/3/2014
WILSON	NIKOLAUS	C	COMMUNITY SERVICE DEPARTMENT	DRIVER/COOK'S ASSISTANT	PB	1/21/2014
JIMENEZ	RONALD	S	COMMUNITY SERVICE DEPARTMENT	MAINTENANCE TECHNICIAN	PB	2/3/2014
DIXON	NICOLE	C	COUNTY ASSESSOR'S OFFICE	APPRAISER	T	1/13/2014
LOVATO	RICO	M	COUNTY CLERK'S OFFICE	VOTER REGISTRATION CLERK	PB	1/21/2014
MARTINEZ	ESTRELLA	F	COUNTY CLERK'S OFFICE	SCANNING & INDEXING TECHNICIAN	PB	1/27/2014
OLIVAS	MANUEL	R	COUNTY CLERK'S OFFICE	SCANNING & INDEXING TECHNICIAN	PB	1/21/2014
FLORES	TONY		COUNTY MANAGER'S OFFICE	ASSISTANT COUNTY MANAGER	E	1/13/2014
GONZALES	MELODY	S	COUNTY MANAGER'S OFFICE	EMPLOYEE BENEFITS COORDINATOR	PB	1/13/2014
QUINTANA	ROBERT	S	COUNTY SHERIFF'S OFFICE	ANIMAL CONTROL OFFICER	PB	2/3/2014
BACA	WILLIAM	T	HOUSING DEPARTMENT	MAINTENANCE SUPERVISOR	PB	1/6/2014
MARTINEZ	ROBERTA	D	HOUSING DEPARTMENT	CLERICAL SPECIALIST	PB	1/22/2014
HE	LITTLE SUN	S	PUBLIC SAFETY DEPARTMENT	THERAPIST	PB	2/4/2014
MONTANO	CAROLYN	E	PUBLIC SAFETY DEPARTMENT	SECRETARY SENIOR	PB	1/6/2014
ORTIZ	AUGUSTINE	M	PUBLIC SAFETY DEPARTMENT	DETENTION OFFICER	PB	1/2/2014
PIFER	KENNETH	D	PUBLIC SAFETY DEPARTMENT	DAY REPORTING SUPERVISOR	PB	1/6/2014
RENNER	MARC	S	PUBLIC SAFETY DEPARTMENT	DETENTION OFFICER	PB	1/2/2014
ROJO	ELIER	I	PUBLIC SAFETY DEPARTMENT	DETENTION OFFICER	PB	1/2/2014
VALDEZ	MANUEL	E	PUBLIC SAFETY DEPARTMENT	DETENTION OFFICER	PB	1/6/2014
HETLER	JAMES	L	PUBLIC SAFETY DEPARTMENT	ACCOUNTING TECH. SENIOR	PB	2/3/2014
QUINTANA	DANIEL	J	PUBLIC SAFETY DEPARTMENT	EMERGENCY COMM SPEC TRAINEE	PB	1/27/2014
WOODS	ASHLEY	D	PUBLIC SAFETY DEPARTMENT	EMERGENCY COMM SPEC TRAINEE	PB	1/27/2014
BACA	JUSTIN	J	PUBLIC WORKS DEPARTMENT	CLERICAL ASSISTANT	T	1/3/2014
DURAN	JEANETTE		PUBLIC WORKS DEPARTMENT	ACCOUNTANT SENIOR	PB	2/3/2014
SALAZAR	ADAM	E	PUBLIC WORKS DEPARTMENT	UTILITIES MAINTENANCE WORKER	PB	2/3/2014
SA LEZ	LORANCE	H	PUBLIC WORKS DEPARTMENT	UTILITIES MAINTENANCE WORKER	PB	2/3/2014

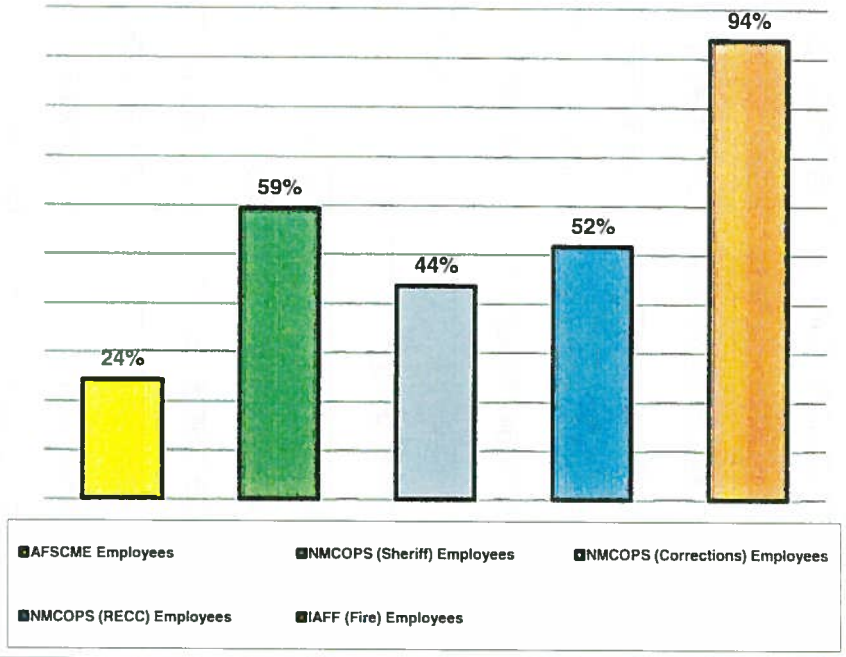
LABOR STATISTICS FOR JANUARY 2014

Union Status		Percentage of Union Status		Number of Employees Paying Dues		Percentage Of Employees Paying Union Dues	
AFSCME Employees	223	AFSCME Employees	26.42%	AFSCME Employees	54	AFSCME Employees	24%
NMCOPS (Sheriff) Employees	59	NMCOPS (Sheriff) Employees	6.99%	NMCOPS (Sheriff) Employees	35	NMCOPS (Sheriff) Employees	59%
NMCOPS (Corrections) Employees	94	NMCOPS (Corrections) Employees	11.14%	NMCOPS (Corrections) Employees	41	NMCOPS (Corrections) Employees	44%
NMCOPS (RECC) Employees	29	NMCOPS (RECC) Employees	3.44%	NMCOPS (RECC) Employees	15	NMCOPS (RECC) Employees	52%
IAFF (Fire) Employees	64	IAFF (Fire) Employees	7.58%	IAFF (Fire) Employees	60	IAFF (Fire) Employees	94%
Total Number of Union Employees	469	Total Percentage of Union Employees	55.57%	Total Number of Employees Paying Dues	205		
Non-Union Employees	375	Non-Union Employees	44.43%				
Total Number of Employees	844		100%				

Union Status



Paying Members



SANTA FE COUNTY HR STATISTICS FOR THE MONTH OF JANUARY 2014

Department	Division	Regular Employees	Part Time Employees	Full Time Employees	Elected/Officials	Temporary Employees	Vacancies	Total Positions	New Hires/Re-employments	Resignations	Retirements	End of term/temp status	Terminations	Total separations
MANAGER'S OFFICE	01-COUNTY MANAGER ADMINIS.	8		8				8	1					
	02-COMMISSION	5		5	5	1		5						
	15-HUMAN RESOURCES	10		10			1	11	1					
	21-FINANCE	22		22			1	23						
CMO TOTAL		45		45	5	1	2	47	2					
	01-LEGAL ADMINISTRATION	8		8				8						
LEGAL TOTAL		8		8				8						
ADMINISTRATIVE SERVICES DEPARTMENT	00-ADMINISTRATION	2		2				2						
	02-INFORMATION TECHNOLOGY	11		11			2	13	1					
	12-PURCHASING	7		7				7						
	16-MAIL ROOM	1		1				1						
	17-RISK MANAGEMENT	3		3				3						
ASD TOTAL		24		24			2	26	1					
COMMUNITY SERVICES DEPARTMENT	01-ADMINISTRATION	3		3				3						
	20-INDIGENT HOSPITAL FUND	3		3				3						
	21-EMS-HEALTH CARE	3		3				3						
	74-MOBILE HEALTH FAIR VAN	3	1	2			2	5						
TOTAL		12	1	11	0	0	2	14	0	0	0	0	0	0

SANTA FE COUNTY HR STATISTICS FOR THE MONTH OF JANUARY 2014

Department	Division	Regular Employees	Part Time Employees	Full Time Employees	Elected/Officials	Temporary Employees	Vacancies	Total Positions	New Hires/Re-employments	Resignations	Retirements	End of term/temp status	Terminations	Total separations
	04-DWI LOCAL	7		7			1	8						
TOTAL		7	0	7	0	0	1	8	0	0	0	0	0	0
	09-DWI TEEN COURT	3		3				3	1	1				1
TOTAL		3	0	3	0	0	0	3	1	1	0	0	0	1
	89-SENIOR PROGRAMS - ADMIN.	11		11			1	12						
	90-SR SVCS-CONGREGATE MEALS	8	1	7		3	2	10	2					
	92-SR SVCS - HOME DELIVERED	1	1				1	3						
	93-SR SVCS - TRANSPORTATION	4		4		1		4						
TOTAL		24	2	22	0	4	5	29	2	0	0	0	0	0
	01-POJOAQUE SATELLITE OFFICE					1								
	02-EDGEWOOD SATELLITE OFFICE					1								
TOTAL						2								
CSD TOTAL		46	3	43	0	6	8	54	3	1	0	0	0	1
	30-ADMINISTRATION	11		11			1	12	2					
	49-HOUSING SECTION 8 VOUCHER	2		2				2						
	82-HOUSING CFP - 2012	1		1				1						
HOUSING TOTAL		14		14			1	15	2					
GROWTH MANAGEMENT DEPARTMENT	01-LAND USE ADMINISTRATION	4		4				4						

SANTA FE COUNTY HR STATISTICS FOR THE MONTH OF JANUARY 2014

Department	Division	Regular Employees	Part Time Employees	Full Time Employees	Elected/Officials	Temporary Employees	Vacancies	Total Positions	New Hires/Re-employments	Resignations	Retirements	End of term/temp status	Terminations	Total separations
	02-PLANNING	6		6			1	7						
	08-REGIONAL PLANNING AUTHORITY													
	14-GIS	7		7			2	9						
	15-AFFORDABLE HOUSING-COUNTY	2		2				2						
	16-BUILDING & DEVELOPMENT	15		15				15						
GMD TOTAL		34		34			3	37						
PUBLIC WORKS DEPARTMENT	00-OFFICE OF THE DIRECTORS	5		5				5						
	01-PUBLIC WORKS ADMIN.	12		12				12						
	02-FLEET SERVICE	8		8			1	9					1	1
	03-TRAFFIC ENGINEERING	6		6			2	8						
	05-SOLID WASTE	21	1	20		1		21						
	11-ROAD MAINTENANCE	35		35			4	39						
TOTAL		87	1	86		1	7	94					1	1
	02-PROPERTY CONTROL	10		10			5	15						
	03-BUILDING SERVICES	16	2	14			2	18						
	18-PROJECT DEVELOPMENT DIV	9		9			1	10						
	26-OPEN SPACE	1		1			4	5						
TOTAL		36	2	34			12	48						

SANTA FE COUNTY HR STATISTICS FOR THE MONTH OF JANUARY 2014

Department	Division	Regular Employees	Part Time Employees	Full Time Employees	Elected/Officials	Temporary Employees	Vacancies	Total Positions	New Hires/Re-employments	Resignations	Retirements	End of term/temp status	Terminations	Total separations
	08-SANTA FE RIVER GREENWAY	1		1				1						
TOTAL		1	0	1	0	0	0	1	0	0	0	0	0	0
	10-WATER	16		16		1	3	19						
	15-AAMODT	1		1				1						
	20-WASTEWATER						1	1						
TOTAL		17		17		1	4	21						
TOTAL		141	3	138	0	2	23	164	0	0	0	0	1	1
PUBLIC SAFETY DEPARTMENT	01-FIRE ADMINISTRATION	27		27			2	29		1				1
	08-EMERGENCY PREPAREDNESS													
	09-FOREST RESTORATION	3		3				3						
	11-FIRE REGIONS	67		67			6	73						
	14-FEMA GRANT	1		1				1						
TOTAL		98		98			8	106		1				1
	01-ADMINISTRATION	9	1	8			2	11						
	60-ADULT FACILITY	129		129			27	156	5	1				1
	62-MAINTENANCE DIVISION	5		5			2	7						
	63-MEDICAL SERVICES	21		21			9	30		1				1
	65-ELECTRONIC MONITORING	9		9				9						

SANTA FE COUNTY HR STATISTICS FOR THE MONTH OF JANUARY 2014

Department	Division	Regular Employees	Part Time Employees	Full Time Employees	Elected/Officials	Temporary Employees	Vacancies	Total Positions	New Hires/Re-employments	Resignations	Retirements	End of term/temp status	Terminations	Total separations
	70-YOUTH DEVELOPMENT FAC.	19		19			10	29	1					
	72-ADOLESCENT RESIDENCE CTR													
	73-DAY REPORTING ASSESSMENT													
TOTAL		192	1	191			50	242	6	2				2
	01-ADMINISTRATION	41		41			7	48	2					
TOTAL		41	0	41	0	0	7	48	2	0	0	0	0	0
PSD TOTAL		331	1	330	0	0	65	396	8	3	0	0	0	3
COUNTY CLERK'S OFFICE	01-REPORTING & RECORDING	18	1	17	1		4	22	2	1				1
	02-BUREAU OF ELECTIONS	10	1	9			2	12	1					
CLERK'S OFFICE TOTAL		28	2	26	1		6	34	3	1				1
10-COUNTY TREASURER DEPT.	01-COUNTY TREASURER ADMIN.	12		12	1			12						
COUNTY ASSESSOR'S OFFICE	01-COUNTY ASSESSOR ADMIN.	29		29	1			29						
	11-PROPERTY VALUATION	14		14		1		14						
ASSESSOR'S OFFICE		43		43	1	1		43						
COUNTY SHERIFF'S OFFICE	01-ADMIN/ANIMAL CNTRL/ENFORC	115		115	1		3	118		1			1	2
	04-REG.III DRUG ENF GRANT-A	2		2				2						
	06-REG III-HIDTA GRANT	1		1				1						
SHERIFF'S OFFICE		118		118	1		3	121		1			1	2

SANTA FE COUNTY HR STATISTICS FOR THE MONTH OF JANUARY 2014

Department	Division	Regular Employees	Part Time Employees	Full Time Employees	Elected/Officials	Temporary Employees	Vacancies	Total Positions	New Hires/Re-employments	Resignations	Retirements	End of term/temp status	Terminations	Total separations
COUNTY PROBATE	01-COUNTY PROBATE JUDGE				1									
COUNTY SURVEYOR	01-ADMINISTRATION													
COUNTY WIDE TOTAL		844	9	835	10	10	113	957	19	6	0	0	2	8

Memorandum

To: Santa Fe Board of County Commissioners

From: Teresa C. Martinez, Finance Director

Via: Katherine Miller, County Manager

Date: February 11, 2014

Re: ***Financial report for the month ending 01/31/2014***

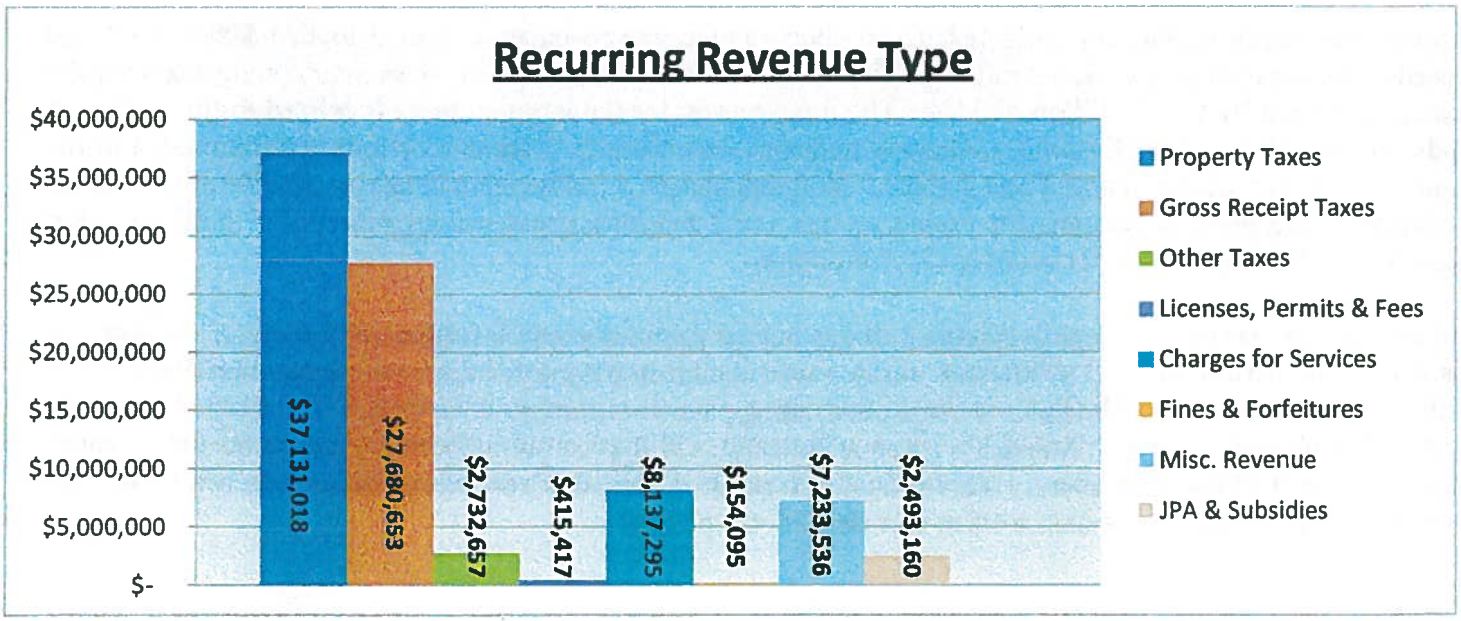
ISSUE:

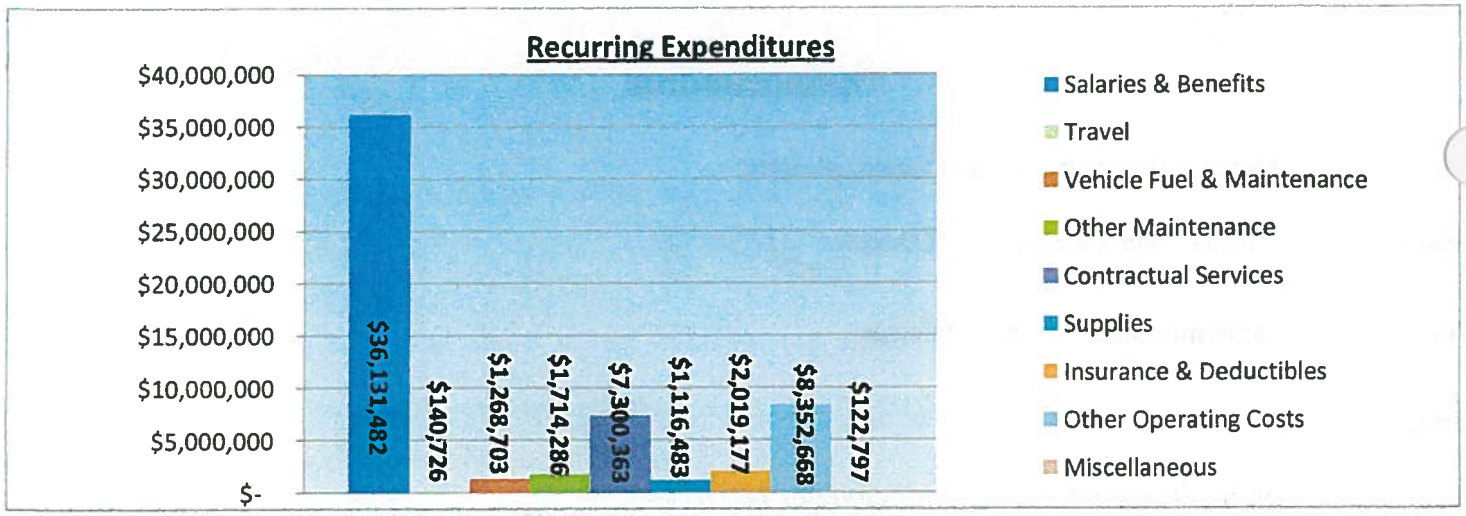
Enclosed is a report summarizing the financial activities of the County through the month ending January 31, 2014.

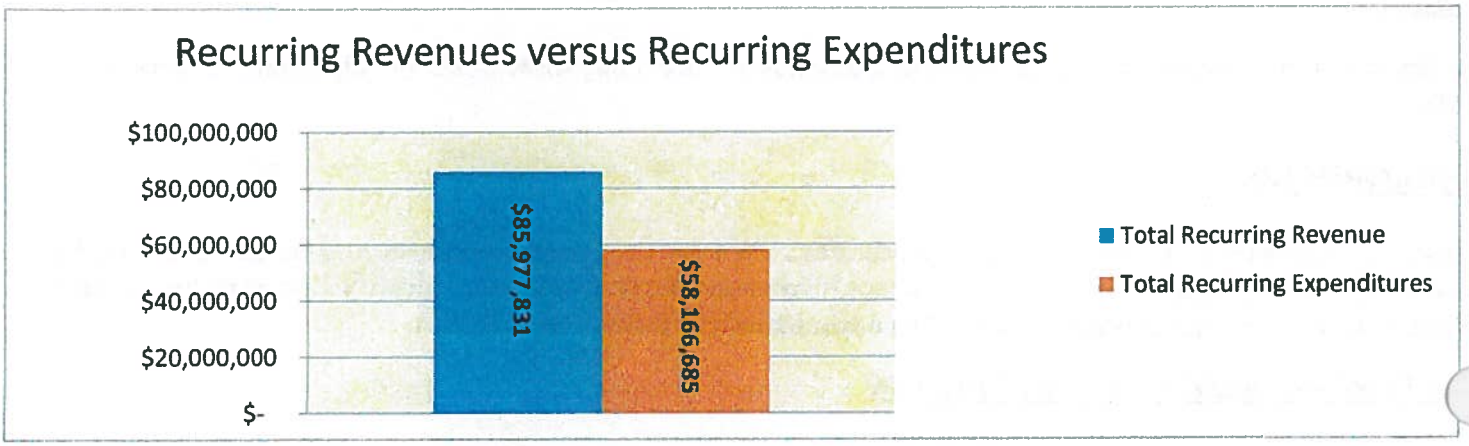
BACKGROUND:

This is a comparison of revenues and expenditures on a recurring versus non-recurring basis. The monthly report will still highlight major revenue sources. Below are several charts that identify 1) the recurring revenue sources, 2) the recurring expenditures and 3) a comparison of the two side by side.

ECURRING VERSUS NON-RECURRING







Through the month of January, as noted in the charts above, the revenues collected totaled $86 million and exceeded the expenditures of $58.2 million. The revenue collections exceed the prior year's collections for the same time period by $11.3 million or 15%. The main reason for the large increase is related to the receipt of funds totaling $5.4 million for the settlement agreement with the U.S. Bureau of Indian Affairs related to the acquisition of Top of the World water rights. The remainder of the revenue increase of $5.92 million can be attributed to increased collections for property taxes ($1.2 million), gross receipt taxes ($1.7 million), other taxes ($556,629) and charges for services ($1.9 million).

The charges for services increase is related to the care of prisoner revenue for the adult facility. Last year, for this same time period, the U.S. Marshal's office was behind in paying for the care of prisoners housed at our facility. Last year the U.S. Marshal's made outstanding payments current in the month of February. We should see that this increase in U.S. Marshal's revenue collections will even out in February and witness the revenues coming in closer to the prior year. This should also result in a smaller revenue increase, which will reduce the amount and percentage of increase when compared to the prior year.

NON-RECURRING EXPENDITURES

Capital expenditures are non-recurring expenditures funded by non-recurring sources. Such sources include bond proceeds, special appropriations, grants and cash balances from excess revenues of prior years. The capital expenditures incurred through the month of January 2014 total $15.8 million.

The following is a listing of some of the major capital expenditures incurred thru the month of January:

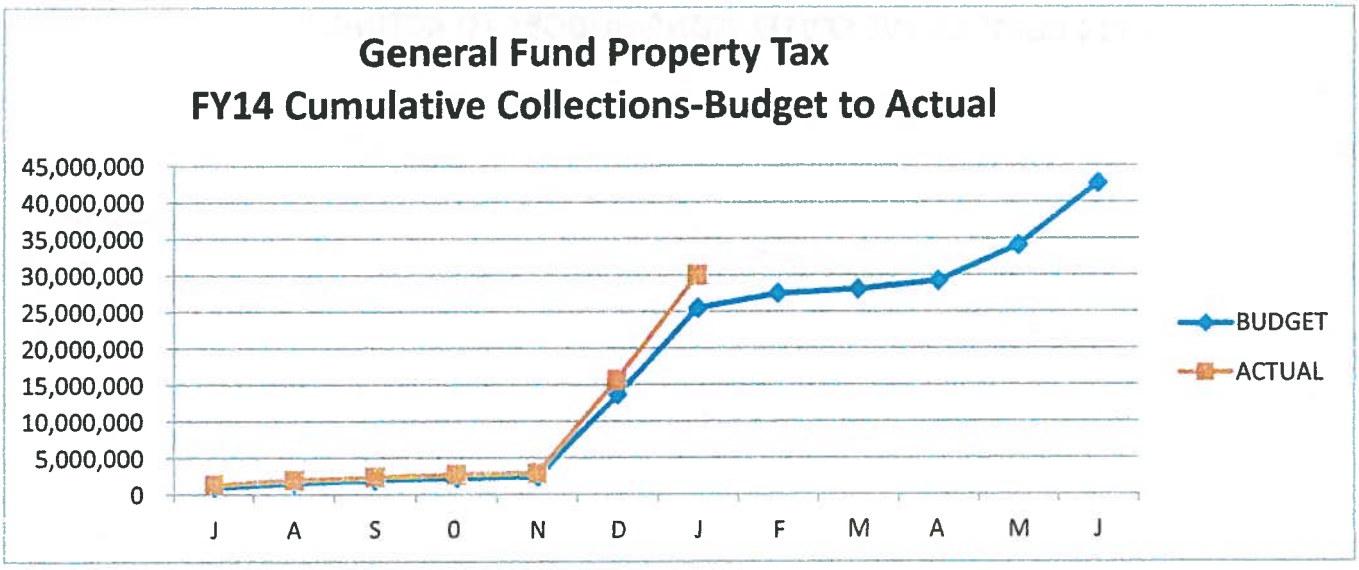
Town of Edgewood Fire Station	$ 896,355	Judicial Court Complex	$ 895,489
Old District Court Bldg	$ 156,148	Corrections Facilities	$ 633,847
Caja Del Rio	$ 1,373,229	Vehicles County-wide	$ 2,545,319
County Road 98	$ 1,080,394	Hale Road	$ 764,355
Eldorado Library	$ 467,250	La Cienega Fire Station	$ 475,718
CR 77-Camino La Tierra	$ 542,732	Western Road	$ 440,071
N. Weimer Road	$ 325,183		

Also included for your information are the charts reflecting major revenue sources and collections through January.

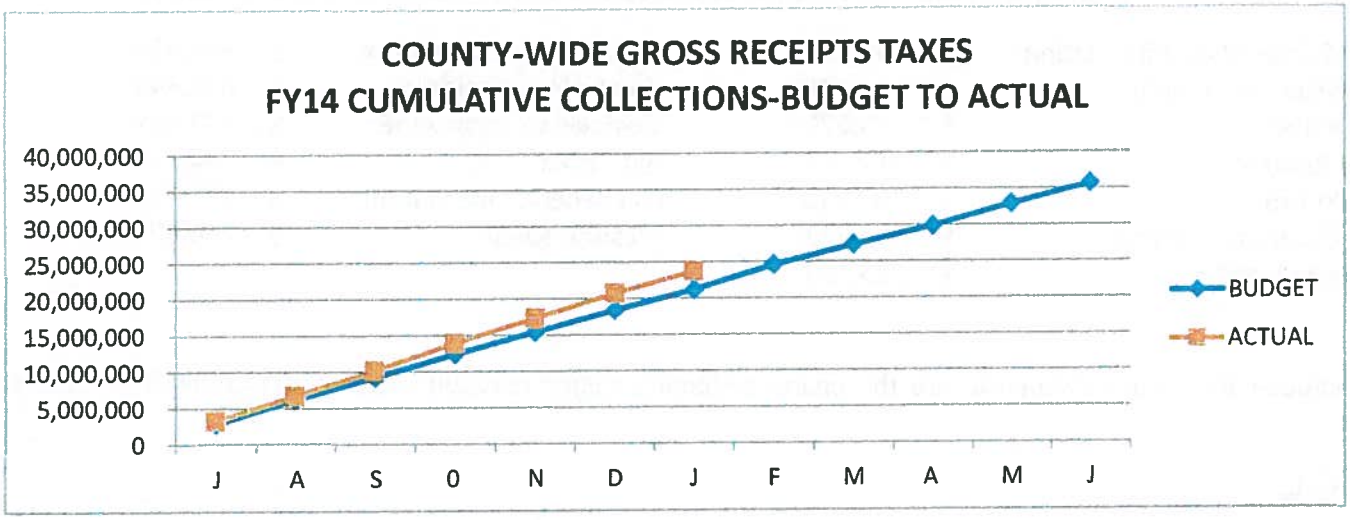
REVENUE:

Property tax is recorded monthly and compared to the actual monthly budget forecasts. Property tax revenue budget estimates are conservative, as a budget shortfall in tax receipts would have a serious impact on various County operations.

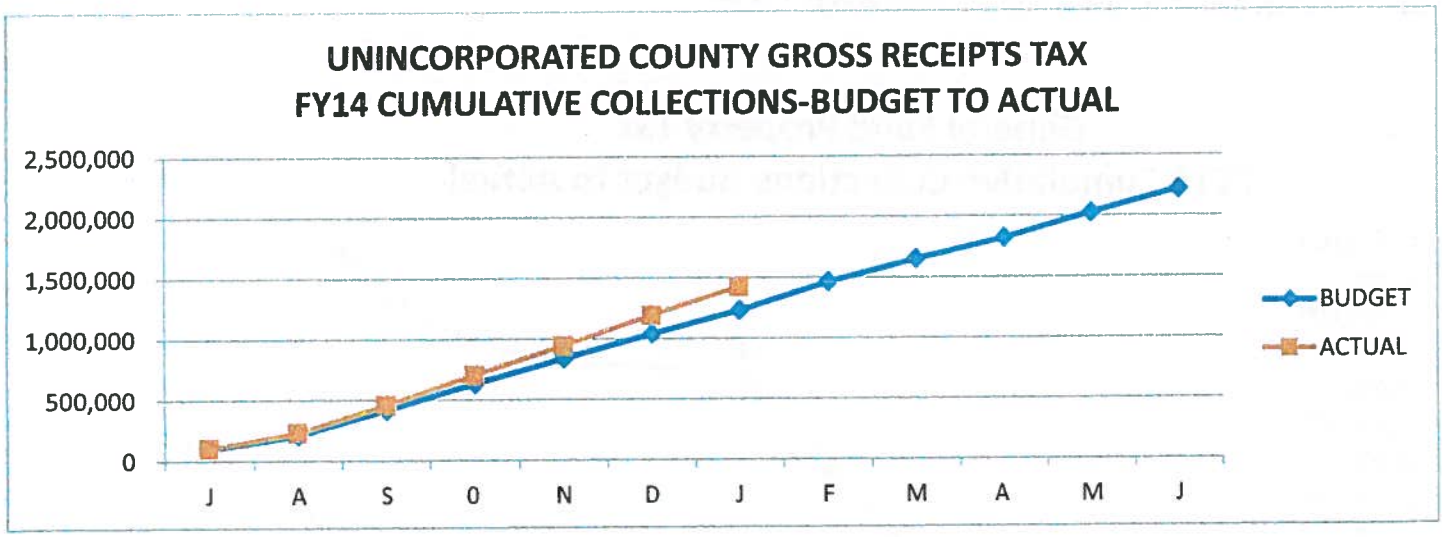
Actual property tax collections of $30.1 million through the end of January exceed the budget of $25.5 million by $4.6 million. The collections are $1.1 million or 3.9% above the prior year's collections for the same time period. The chart below includes collections through January.



The gross receipts taxes are estimated from trend data and from economic analysis of the business activities in the areas of construction, wholesale, retail and service sectors. Combined, both the county-wide and the unincorporated gross receipt taxes collected through January total $25.1 million and are $2.7 million greater than or 12% above the budgeted amount of $22.4 million. January collections were greater than the collections of the prior year by $2.1 million or 9.3% for the same time period.



The actual unincorporated GRT collections began to rebound in FY 2013. In FY 2014 the total unincorporated GRTs for January are above budget by $196,297. The unincorporated GRT collections total $1.4 million through January and are $662,785 above the prior year collections. The increase is mainly attributable to the enacted Fire Excise Tax which began receiving monthly collections in September resulting in an average monthly amount of $100,000 to $115,000. Through January, the Fire Excise GRT collections total $579,678.



SUMMARY:

The FY 2015 budget kick-off is scheduled for February 24th. At this meeting, the budget directions for FY 2015 will be distributed. Much of the planning for next fiscal year is contingent upon actions taken at the legislative session.

In particular, County Staff is following closely the Legislative action as it relates to the Safety Net Care Pool (previously known as Sole Community Provider) and the Hold-Harmless GRT. The Legislature is pursuing funding the Safety Net Care Pool with either a 1/12th increment or a 1/8th increment. A 1/12th increment would equate to approximately $3.3 million a year for the County. A 1/8th increment would equate to approximately $4.2 - $4.5 million a year. Lastly, staff will be coordinating budget discussion meetings with the commissioners and setting budget study schedule(s).

MEMORANDUM

DATE: February 17, 2014

TO: Board of County Commissioners

FROM: Julia Valdez, Constituent Services Liaison, Manager's Office

VIA: Katherine Miller, County Manager

ITEM AND ISSUE: ORDINANCE NO. 2014-___

(Amending and Restating Ordinance 2002-08, An Ordinance Governing Tobacco Products Placement, Distribution, Display, and Sales and Establishing Penalties For Violation) To Ensure Conformity with State Law, to Regulate E-Cigarette Sales to Minors and to Insert a Severability Clause (Commissioner Stefanics and Commissioner Anaya)

BACKGROUND

Electronic nicotine delivery systems or, e-cigarettes, are battery-powered heating elements that are designed to deliver nicotine in the form of a vapor. E-cigarette cartridges are available in a variety of flavors such as bubblegum, chocolate and mint that appeal to youth. They are seen as gateway products to tobacco abuse and nicotine addiction.

The Centers for Disease Control and Prevention released data that shows the percentage of middle and high school students that tried e-cigarettes more than doubled between 2011 and 2012. 76% of young people who currently use e-cigarettes also smoked regular cigarettes, leading experts to conclude that e-cigarettes may lead to smoking real cigarettes.

E-cigarettes simulate smoking and are increasingly popular with young people. Currently the public has no guarantees on how they're made, what toxins they may contain or how many they emit. E-cigarettes should be kept out of the hands of children to help keep our community healthy.

Minors under 18 years of age are already prohibited from buying cigarettes and other tobacco products.

SANTA FE COUNTY

ORDINANCE NO. 2014-___

AMENDING AND RESTATING ORDINANCE 2002-08, (AN ORDINANCE GOVERNING TOBACCO PRODUCTS PLACEMENT, DISTRIBUTION, DISPLAY, AND SALES AND ESTABLISHING PENALTIES FOR VIOLATION) TO ENSURE CONFORMITY WITH STATE LAW, TO REGULATE E-CIGARETTE SALES TO MINORS AND TO INSERT A SEVERABILITY CLAUSE

WHEREAS, approximately 434,000 Americans die each year of diseases caused by cigarette smoking;

WHEREAS, the Surgeon General of the Public Health Service has determined that smoking is the leading cause of preventable death in this country;

WHEREAS, the Surgeon General, the U.S. Department of Health and Human Services, and the Institute of Medicine have concluded that youth access to tobacco products, especially illegal tobacco sales to minors through retail outlets, is a major contributing factor to tobacco use and addiction among children and adolescents;

WHEREAS, nicotine in tobacco has been found by the Surgeon General's report entitled "The Health Consequences of Smoking: Nicotine Addiction" to be a powerfully addictive drug, and it is therefore important to prevent young people from using nicotine;

WHEREAS, most adults who smoke wish to quit, a majority of current adult smokers have tried to quit without success, and one-half of all teenagers who have been smoking for five years or more have made at least one serious but unsuccessful attempt to quit;

WHEREAS, every day more than 3,000 minors begin smoking: one-half of smokers begin smoking before the age of 18, and 90 percent begin smoking before the age of 21;

WHEREAS, one-third of New Mexico students have smoked cigarettes in the past month;

WHEREAS, present methods of prohibiting tobacco sales and distribution to minors have proven ineffective in preventing tobacco sales and distribution to minors;

WHEREAS, it is in the interest of the public health to regulate the manner of sale and distribution of tobacco products in Santa Fe County in order to promote retailer compliance with the Tobacco Products Act prohibiting tobacco sales to minors, and to promote the health, safety and welfare of the residents of Santa Fe County and minors under eighteen (18) years of age;

WHEREAS, the County may enact an ordinance regulating the sale and distribution of tobacco products intended for smoking pursuant to the authority set forth in the "Tobacco Products Act", NMSA 1978, Section 30-49-1 *et seq.* and may also enact an ordinance to protect the public health, safety and welfare pursuant to NMSA 1978 Section 4-37-1;

WHEREAS, the County is authorized to enact an ordinance on the sale of tobacco products to persons under the age of eighteen (18) years, pursuant to NMSA 1978, Section 30-49-1, *et. seq.*;

WHEREAS, according to the Centers for Disease Control and Prevention the use of e-cigarettes is on the rise among minors, increasing from 4.7% of students who had tried e-cigarettes in 2011 to 10% in 2012, and confirming that 1.78 million middle and high school students nationwide tried e-cigarettes in 2012;

WHEREAS, according to a 2009 report from the U.S. Food and Drug Administration (the FDA), laboratory analysis of e-cigarette products disclosed nicotine, carcinogens and toxic chemicals;

WHEREAS, the U.S. Department of Health and Human Services has concluded that nicotine is as addictive as cocaine or heroin;

WHEREAS, use of e-cigarettes, which contain nicotine, can lead minors into a nicotine addiction that may lead to daily use of tobacco;

WHEREAS, e-cigarettes are not approved by the FDA as smoking cessation devices;

WHEREAS, according to a 2009 publication from the FDA the testing of certain e-cigarette cartridges revealed that the quality control processes used to manufacture the products were inconsistent or non-existent, that cartridges which were labeled non-nicotine actually contained nicotine, and that there were deviations from the contents claimed on the label;

WHEREAS, according to a 2012 study, the use of an e-cigarette for five minutes was found to have immediate adverse physiological effects similar to some of the effects seen with tobacco smoking (*Short-Term Pulmonary Effects of Using an Electronic Cigarette*, Vardavas CI, Anagnostopoulos N, Kougias M, Evangelopoulou V, Connolly GN, Behrakis PK., Journal fo the American College of Chest Physicians, 2012; 141(6):1400-1406);

WHEREAS, nicotine raises the heart rate, increases blood pressure, increases cardiac output and constricts blood vessels, all of which lead to long-term hypertension and heart diseases like congestive heart failure and arrhythmias (*Cardiovascular Toxicity of Nicotine: Implications for Nicotine Replacement Therapy,*Neal L. Benowitz, MD, Steven G. Gourlay, MB, BS, PhD, Journal of the American College of Cardiology, Vol.29, No.7, pages 1422-31, June 1997);

WHEREAS, the liquid used in e-cigarettes: generally contains nicotine and may appeal to young children because of flavorings like strawberry, chocolate and gummy bear; is sold in canisters which do not contain child-resistant caps; is sold in canisters which may contain lethal amounts of nicotine for young children (*Novel Nicotine Delivery Systems and Public Health: The Rise of the E-Cigarette,* Nathan K. Cobb, MD, M. Justin Byron, MHS, David B. Abrams, PhD, and Peter G. Shields, MD, American Journal of Public Health, December 2010, 100(12):2340-2342);

WHEREAS, the estimated lethal dose of nicotine for a child is 10 mg, but a cartridge for an e-cigarette may contain a lethal dose of up to 20 mg of nicotine, and the refill canisters can contain as much as one gram of nicotine (*E-cigarette or Drug Delivery Device? Regulating Novel Nicotine Products,* Nathan K. Cobb, M.D., and David B. Abrams, Ph.D, The New England Journal of Medicine, July 2011);

WHEREAS, a study showed that between 2006 and 2008, 13,700 poisonings from tobacco ingestion occurred in children under 6 years of age (*E-Cigarettes: A Rapidly Growing Internet Phenomenon,* Cyrus K. Yamin, Asaf Bitton, MD, MPH, David W. Bates, MD, MSc, Annals of Internal Medicine, 2010;153:607-609); and

WHEREAS, the serious findings demonstrate that tobacco products and e-cigarettes should be regulated to prevent and prohibit sales to minors.

NOW, THEREFORE, be it resolved by the Board of County Commissioners of Santa Fe County that:

1. Authority.

This Ordinance is enacted pursuant to the authority in NMSA 1978, § 4-37-1 (1975) (as amended) to make and publish any ordinance to discharge the powers not inconsistent with statutory or constitutional limitations placed on counties and to exercise powers that are necessary and proper to provide for the safety, preserve the health, promote the prosperity and improve the morals, order, comfort and convenience of the County's inhabitants, and NMSA 1978, § 4-37-3 (1993) (as amended) which permits prosecution of violations of County ordinances in any court of competent jurisdiction. This Ordinance is also enacted pursuant to NMSA 1978, § 30-49-1 *et seq.*, which authorizes the County to enact an ordinance on regulating the sale and distribution of tobacco products intended for smoking.

2. Definitions.

A. **E-cigarette**. Any product containing or delivering nicotine or any substance intended for human consumption that can be used by a person to simulate smoking through inhalation of vapor or aerosol from the product. E-cigarette includes any component part of such product whether or not sold separately. E-cigarette does not include any product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product and is being marketed and sold solely for the approved purpose.

B. **Minor**. An individual who is less than eighteen years of age;

C. **Self-service display**. A display to which the public has access without the assistance of the seller or the seller's employee.

3. Display Signs.

A person, firm, corporation, partnership or other entity engaged in the retail sale of tobacco products shall obtain and display signs prominently in the place where tobacco products are sold and where a tobacco product vending machine is located. The signs shall reads as follows:

A. A person less than 18 years of age who purchases a tobacco or e-cigarette product is subject to a fine of up to $300;

B. A person who sells a tobacco or e-cigarette product to a person less than 18 years of age is subject to a fine of up to $300.

4. Prohibited sales: Regulations of the Manner of Sale and Distribution of Tobacco Products.

A. No person shall knowingly sell, offer to sell, barter or give any tobacco product to a minor.

B. No person shall sell, offer to sell or deliver a tobacco product in a form other than an original factory-sealed package.

C. No person shall sell a tobacco product to a person who is unable to produce an identity card as evidence that the person is eighteen years of age or over, unless the person appears without reasonable doubt to be over the age of eighteen. Any person selling goods at retail or wholesale may refuse to sell tobacco products to any person who is unable to produce an identity card as evidence that the individual is eighteen years of age or over.

5. Self-Service Tobacco Merchandising.

No person who owns, operates or manages a business where tobacco products are sold, nor any person who sells or offers for sale tobacco products, shall:

A. Sell, permit to be sold, offer for sale, display for sale, or store any tobacco product by means other than vendor assisted sales;

B. Maintain any devices that automatically dispense tobacco products, except that tobacco products may be sold by vending machines in the following locations:

i. In locations not held open to the public, including controlled areas within factories, businesses and offices;

ii. In locations in which the vending machine is equipped with a remote-controlled lock-out device; or

iii. In age-controlled locations where minors are not permitted unless accompanied by a parent or guardian.

C. An owner of a device that violates this provision shall remove said device within three months of the effective date of this Ordinance.

6. Sampling.

It shall be unlawful for any person to engage in distributing free samples of a tobacco product to a person under 18 years of age, except that this provision shall not apply to an individual who provides free samples of tobacco products to a family member or to an acquaintance on private property not held open to the public.

7. Minors.

A. No person under the age of eighteen (18) years of age shall procure or attempt to procure any tobacco product for his/her own use or for use by any other minor.

B. No minor shall present any written, printed or photostatic evidence of age or identity that is false for the purpose of procuring or attempting to procure any tobacco products.

8. Evidence of Age and Identity.

Evidence of the age and identity of the person may be shown by any document that contains a picture of the person issued by a federal, state, county or municipal government, including a motor vehicle driver's license or an identification card issued to a member of the armed forces.

9. E-cigarettes.

All provisions of this Ordinance governing tobacco products shall also govern e-cigarettes and the liquid utilized in e-cigarettes.

10. Penalty.

A. A violation of any of the provisions of this Ordinance by any person over the age of eighteen (18) years shall be punishable by a fine of up to three hundred dollars ($300), imprisonment of up to ninety days, or both a fine and imprisonment.

B. A violation of this Ordinance by any person under the age of eighteen (18) years shall be punished by a fine not to exceed one hundred dollars ($100), forty-eight (48) hours of community service or both a fine and community service.

11. Severability.

The requirements and provisions of this Ordinance are severable. In the event that any requirement, provision, part, subpart or clause of this Ordinance, or the application thereof to any person or circumstance, is held by a court of competent jurisdiction to be invalid or unenforceable, it is the intent of the Board that the remainder of the Ordinance be enforced to the maximum extent possible consistent with the objective of preventing the sale of tobacco products and e-cigarettes to minors.

APPROVED, ADOPTED AND PASSED this ____ day of _____, 2014.

BOARD OF COUNTY COMMISSIONERS

_____
Daniel W. Mayfield, Chair

ATTEST:

_____
Geraldine Salazar, County Clerk

APPROVED AS TO FORM:

_____
Stephen C. Ross, County Attorney

TOBACCO FACT SHEET

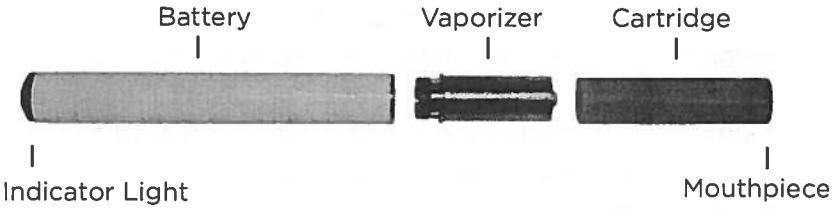
ELECTRONIC CIGARETTES (E-CIGARETTES)

LEGACY
FOR LONGER HEALTHIER LIVES

Electronic cigarettes (e-cigarettes or e-cigs), known formally as electronic nicotine delivery systems (ENDS), are devices designed to look similar to cigarettes in shape, size, and general appearance.[1] They operate by vaporizing a solution containing nicotine, creating a mist that is then inhaled.[1] The tips of these devices often have an indicator light, designed to emulate the burning ash of a traditional cigarette.[1] According to product manufacturers, e-cigarette cartridges are available in various flavors, such as vanilla,[2] menthol,[2] and piña colada,[2] and varying claimed levels of nicotine.[1] Using an e-cigarette is commonly referred to as "vaping."[1] Popular brands of e-cigarettes, sold at convenience stores and gas stations, include "blu" and "NJOY."

BACKGROUND

- The components of a typical e-cigarette are illustrated below:



- Cartridges generally contain up to 20 mg of nicotine.[3]
- Some users refill their own cartridges, which may be dangerous because it involves dealing with potentially dangerous concentrations of nicotine.[4] Refill bottles contain up to 7 grams of nicotine;[5] the fatal dose of nicotine in adults is estimated at 30–60 mg while for children it is estimated at only 10 mg[6] — or approximately 4 drops of a maximum strength refill solution. This risk is more consistent with nicotine-based pesticides, rather than traditional tobacco products and pose a danger via inhalation, ingestion, and skin contact.[7]

PREVALENCE

- Between 6.4% and 7.1% of current smokers have ever used an e-cigarette, compared to ever use of e-cigarettes among never smokers (less than 1.0%).[8]

SAFETY & QUALITY

- On July 22, 2009 the U.S. Food and Drug Administration's (FDA) Division of Pharmaceutical Analysis analyzed the ingredients in a small sample of cartridges from two leading brands of e-cigarettes and found that the tested products contained detectable levels of known carcinogens and toxic chemicals. Diethylene glycol, a potentially lethal organic compound,[9] was found in one cartridge, while nitrosamines were detected in several cartridges.[10]
- Other important findings from the FDA include the following:
  - The quality control processes used to manufacture e-cigarettes seem to be inconsistent or non-existent. Three different e-cigarette cartridges with the same label were tested and each emitted a distinct amount of nicotine with each puff.[9]

- In all but one, the e-cigarette cartridges that were labeled as containing no nicotine had low levels of nicotine.[9]
- The vapor from one high-nicotine cartridge delivered twice as much nicotine when inhaled than was delivered by the control, a sample of FDA-approved nicotine inhalation products.[9]

- Studies[11,12] suggest adverse effects associated with e-cigarettes, but additional non-biased national and international research is needed to understand the effects of both short- and long-term use.

LEGAL STATUS & REGULATION

- The FDA attempted to regulate e-cigarettes as drug-delivery devices but failed after the courts determined that e-cigarettes were properly regulated under the FDA's tobacco authority pursuant to the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA) and not the FDA's drug delivery device authority.[13,14]
- In April 2011, the FDA issued a statement announcing that they intend to regulate e-cigarettes as "tobacco products." This includes: (1) marketing restrictions, (2) mandated ingredient listing, and (3) pre-market review.[12] However, to date, FDA has not asserted its authority over e-cigarettes and they remain unregulated.
- Several state and local governments, including New Jersey[15] and King County, Washington,[16] have included or are in the process of adding e-cigarettes to their smoking bans. Additionally, the U.S. Department of Transportation has proposed banning the use of e-cigarettes on planes.[17] However, several airlines have prohibited smoking e-cigarettes on their aircrafts on their own accord.[18,19]
- California, Minnesota, New Hampshire, New Jersey, New York, Kansas, Vermont, and Utah have prohibited the sale of e-cigarette to minors since March 2011.[20]

MARKETING & COMMERCIAL APPEAL

- The e-cigarette companies advertise their products as a better-smelling, cheaper, and guilt-free alternative to smoking.[21] They are also marketed as a way to circumvent some smoking bans.[22]
- E-cigarettes are promoted heavily online[1,23] and are more widely searched than snus and NRTs (nicotine replacement therapy).[19]
- There is concern that e-cigarettes may appeal to youth because of their high-tech design, easy availability online or via mall kiosks, and the wide array of flavors of cartridges.[24]

ATTITUDES & CONCERNS

- A nationally-representative survey found that 40.2% of Americans have heard of e-cigarettes and more than 70.0% of smokers believe that e-cigarettes are less harmful than regular cigarettes.[25]
- The most commonly cited reasons for use by e-cigarette users include: the perception that they are healthier/less toxic than traditional cigarettes, aid in tobacco craving/withdrawal symptoms, smoking cessation facilitator, and relapse avoidance.[26]
- In addition to the health concerns cited above, recent studies suggest that e-cigarettes could be worrisome regarding relapse of former smokers,[27] the "re-normalization" of tobacco,[23] and a gateway for cigarettes.[23,28] It is also thought that e-cigarettes can contribute to tobacco use by allowing smokers to use nicotine despite ever-increasing smoking bans (dual use).[22] Since they recently emerged on the market, however, more research must be done to fully understand the consequences.
- The World Health Organization (WHO) expressed concern with e-cigarettes, stating they may undermine tobacco control efforts, such as smoking bans and FDA-approved NRTs. Several countries, including Australia, China, and Brazil have banned the sale and marketing of e-cigarettes.[29]

[1] Kuschner, WG, Reddy, S, Mehrotra, N, Paintal, HS. Electronic cigarettes and thirdhand tobacco smoke: Two emerging health care challenges for the primary care provider. *InInt J Gen Med.* 2011;4:115-120. doi: 10.2147/IJGM.S16908.
[2] Flavored cartridges (2012). blu Cig Web site. Available at: http://www.blucigs.com/cartridges. Accessed June 29, 2012.
[3] Cobb NK, Abrams DB. E-cigarette or drug-delivery device? Regulating novel nicotine products. *N Engl J Med.* 2011;365(3):193-195.
[4] Yamin, CK, Bitton, A, Bates, DW. E-cigarettes: A rapidly growing internet phenomenon. *Ann Intern Med.* 2010;153:607-609.
[5] 100ml titanium ice 72mg unflavored - single bottle (5/29/2012). Totally Wicked E-Liquid Web site. Available at: http://www.totallywicked-eliquid.com/products/totally-wicked-eliquid/titanium-ice-72mg-eliquid/100ml-titanium-ice-72mg-unflavored-2-product.html. Accessed June 20, 2012.
[6] International Programme on Chemical Safety, INCHEM. Nicotine. http://www.inchem.org/documents/pims/chemical/nicotine.htm#SubSectionTitle:7.2.1 Human data. Published March, 1991. Accessed June 15, 2012.
[7] Cobb, NK, Byron, J, Abrams, DB, Shields, PG. Novel nicotine delivery systems and public health: The rise of the "e-cigarette". *Am J Public Health.* 2010;100(12):2340-2342. doi: 10.2105/AJPH.2010.199281.
[8] Pearson, JL, Richardson, A, Niaura, RS, Vallone, DM, Abrams, DB. E-Cigarette awareness, use, and harm perceptions in U.S. adults. *Am J Public Health.* 2012;102(9);1758-1766. doi: 10.2105/AJPH.2011.300526.
[9] Wax, PM. Elixirs, diluents, and the passage of the 1938 federal Food, Drug, and Cosmetic Act. *Ann Intern Med.* 1995;122;456-461.
[10] U.S. Food and Drug Administration, Division of Pharmaceutical Analysis. Evaluation of e-cigarettes. www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf. Accessed June 13, 2012.
[11] Vardavas, CI, Anagnostopoulos, N, Kougias, M, Evangelopoulou, V, Connolly, GN, Behrais, PK. Short-term pulmonary effects of using an electronic cigarette: Impact on respiratory flow resistance, impedance, and exhaled nitric oxide. [published online ahead of print December 22, 2011]. *CHEST.* 2012;141:1400-1406. doi: 10.1378/chest.11-2443.
[12] McCauley, L, Markin, C, Hosmer, D. An unexpected consequence of electronic cigarette use. *CHEST.* 2012;141:1110-1113. doi: 10.1378/chest.11-1334
[13] Sottera v. FDA, 627 F. 3d 891 (D.C. Cir. 2010)
[14] Deyton, LR, Woodcock, J. Regulation of e-cigarettes and other tobacco products. Letter to stakeholders. U.S Food and Drug Administration Web site. 2011. http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm. Accessed June 13, 2012.
[15] Blumenfeld, K. Electronic cigarettes (E-cigarettes). http://www.njgasp.org/E-Cigs_White_Paper.pdf. Published June 2012. Accessed June 29, 2012.
[16] Metropolitan King County Council. Board of Health approves electronic cigarette regulations. 2010. http://www.kingcounty.gov/council/news/2010/December/JP_Ecig.aspx. Accessed June 15, 2012.
[17] Smoking of electronic cigarettes on aircraft, Final Rule, 76 Fed. Reg. 57008-57012 (September 15, 2011) (to be codified at 14 C.F.R. pt. 252).
[18] JetBlue Airlines. Electronic/Smokeless Cigarettes. Retrieved June 6, 2013, from http://help.jetblue.com/SRVS/CGI-BIN/webisapi.dll/,/?St=276,E=0000000000113349029,K=9756,Sxi=1,Case=obj%28395995%29
[19] American Airlines. 2008. Keeping Passengers and Employees Safe at All Times. Retrieved June 6, 2013, from http://www.aa.com/i18n/amrcorp/corporateInformation/facts/safety.jsp
[20] American Lung Association. State Legislated Actions on Tobacco Issues 2010. http://www.lungusa2.org/slati/reports/SLATI_2010_Final_Web.pdf. Accessed June 21, 2012.
[21] Green Smoke. Green Smoke Web site. http://www.greensmoke.com/. 2012. Accessed June 21, 2012.
[22] U.S. Food and Drug Administration. Transcript for FDA's media briefing on electronic cigarettes (July 22, 2009). Available at: http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm. Accessed June 21, 2012.
[23] Ayers, JW, Ribisl, KM, Brownstein, JS. Tracking the rise in popularity of electronic nicotine delivery systems (electronic cigarettes) using search query surveillance. *Am J Prev Med.* 2011;40(4):448-453. http://archive.tobacco.org/news/314895.html. Accessed June 13, 2012.
[24] U.S. Food and Drug Administration. FDA and public health experts warn about electronic cigarettes [press release]. July, 2009. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm. Accessed June 15, 2012.
[25] Pearson, JL, Richardson, A, Niaura, RS, Vallone, DM, Abrams, DB. E-Cigarette awareness, use, and harm perceptions in U.S. adults. *Am J Public Health.* 2012;102(9);1758-1766. doi: 10.2105/AJPH.2011.300526.
[26] Etter, J-F, Bullen, C. Electronic cigarette: User profile, utilization, satisfaction and perceived efficacy. *Addiction.* 2011;106:2017-2028. doi: 10.1111/j.1360-0443.2011.03505.
[27] McMillen, R, Maduka, J, Winickoff, J. Use of emerging tobacco products in the United States. *J Environ Public Health.* 2012;2012(Article ID 989747):8 pages. doi: 10.1155/2012/989474.
[28] Regan, AK, Promoff, G, Dube, SR, Arrazola, R. Electronic nicotine delivery systems: Adult use and awareness of the 'e-cigarette' in the U.S.A. [published online ahead of print October 27, 2011]. *Tob Control.* 2011. doi: 10.1136/tobaccocontrol-2011-050044.
[29] WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: Third report of a WHO study group. whqlibdoc.who.int/publications/2009/9789241209557_eng.pdf. Accessed June 13, 2012.

Original Research: TOBACCO CESSATION AND PREVENTION | June 2012

Short-term Pulmonary Effects of Using an Electronic Cigarette: Impact on Respiratory Flow Resistance, Impedance, and Exhaled Nitric Oxide FREE TO VIEW

Constantine I. Vardavas, MD, MPH, PhD; Nektarios Anagnostopoulos, MD; Marios Kougias, MD; Vassiliki Evangelopoulou, MD; Gregory N. Connolly, DMD, MPH; Panagiotis K. Behrakis, MD, PhD, FCCP

From the Center for Global Tobacco Control(Drs Vardavas, Connolly, and Behrakis), Department of Society, Human Development, and Health, Harvard School of Public Health, Boston, MA; the Smoking and Lung Cancer Research Center (Drs Vardavas, Anagnostopoulos, Kougias, Evangelopoulou, and Behrakis), Hellenic Cancer Society, Athens, Greece; and the Laboratory of Respiratory Physiology (Drs Anagnostopoulos, Kougias, and Behrakis), Department of Medicine, University of Athens, Greece.

For editorial comment see page 1371

Funding: This project was partially supported by internal funds of the Hellenic Cancer Society, Greece.

Chest. 2012;141(6):1400-1406. doi:10.1378/chest.11-2443

Abstract

Background: Debate exists over the scientific evidence for claims that electronic cigarettes (e-cigarettes) have no health-related ramifications. This study aimed to assess whether using an e-cigarette for 5 min has an impact on the pulmonary function tests and fraction of exhaled nitric oxide (FENO) of healthy adult smokers.

Methods: Thirty healthy smokers (aged 19-56 years, 14 men) participated in this laboratory-based experimental vs control group study. Ab lib use of an e-cigarette for 5 min with the cartridge included (experimental group, n = 30) or removed from the device (control group, n = 10) was assessed.

Results: Using an e-cigarette for 5 min led to an immediate decrease in FENO within the experimental group by 2.14 ppb (P = .005) but not in the control group (P = .859). Total respiratory impedance at 5 Hz in the experimental group was found to also increase by 0.033 kPa/(L/s) (P < .001), and flow respiratory resistance at 5 Hz, 10 Hz, and 20 Hz also statistically increased. Regression analyses controlling for baseline measurements indicated a statistically significant decrease in FENO and an increase in impedance by 0.04 kPa/(L/s) (P = .003), respiratory resistance at 5 Hz by 0.04 kPa/(L/s) (P = .003), at 10 Hz by 0.034 kPa/(L/s) (P = .008), at 20 Hz by 0.043 kPa/(L/s) (P = .007), and overall peripheral airway resistance (β, 0.042 kPa/[L/s]; P = .024), after using an e-cigarette.

Conclusions: e-Cigarettes assessed in the context of this study were found to have immediate adverse physiologic effects after short-term use that are similar to some of the effects seen with tobacco smoking; however, the long-term health effects of e-cigarette use are unknown but potentially adverse and worthy of further investigation.

Electronic cigarettes (e-cigarettes) are marketed as potentially reduced tobacco exposure products. The product resembles, but is not, a cigarette in design or function and is marketed as "safer" than a conventional cigarette. However, debate exists over the scientific evidence for the claims that the products have no health-related ramifications. Because e-cigarettes do not contain or burn tobacco, they do not appear to deliver the known toxins found in conventional cigarette smoke.[1-4] Conversely,

US Food and Drug Administration (FDA) analyses have indicated that e-cigarettes contain a number of toxins and carcinogens, including tobacco-specific nitrosamines, diethylene glycol, and other components suspected of being harmful to humans.[5]

Because of the increase in interest regarding e-cigarettes and they claims that they are potentially reduced-exposure product, a nicotine-delivery device, or a smoking-cessation tool, it is imperative to assess the risks related to alternative nicotine delivery systems to protect public and consumer health.[6-10] Previous research has indicated that smokers have significantly higher lung resistances at 5 Hz and 20 Hz and lower concentrations of fraction of exhaled nitric oxide (FENO)—a noninvasive marker of bronchial inflammation—compared with nonsmokers.[11,12] To date, there is no published evidence of any direct health-related effect of acute physiologic response to using an e-cigarette; thus, the aim of the current study was to investigate whether using an e-cigarette ab lib for 5 min could affect respiratory mechanics and FENO within the context of an experimental vs control group study design.

Materials And Methods

Our study sample was composed of 30 adults (14 men, 16 women) of a mean age of 34.8 years (range 19-56 years) recruited from a community setting in Athens, Greece. All subjects were smokers with a minimum pack-year index of 5. Exclusion criteria included any chronic and/or lung disease (including history of bronchial asthma or bronchial hyperreactivity), acute illness during the previous 2 weeks, current pregnancy or lactation, or current use of any medication. All subjects were instructed not to eat or drink any kind of beverages for at least 2 h prior to the examination and to avoid smoking during the prior 4 h.

A laboratory-based intervention study design was applied, within which two groups were created: the experimental group (n = 30) and the control group (n = 10). The 10 participants of the control group were randomly selected from the experimental group and, in a different session, participated in the experimental group. The role of using an e-cigarette was assessed through (1) comparing the changes noted among control group participants with changes noted among experimental group participants after the intervention (intragroup comparison), and (2) comparing pre vs post respiratory function among experimental group participants (intergroup comparison). The subjects enrolled in the experimental group were instructed to use the e-cigarette ad lib for 5 min as they would usually smoke. The control group subjects were asked to use the e-cigarette with similar frequency, but without the e-cigarette cartridge included; therefore, e-cigarette vapor was not created nor inhaled. As vapor was not formed in the control setting, blinding was not possible.

The ethics committee of the Hellenic Anti-Cancer Society, Athens, Greece, provided ethics approval (protocol number: 67-7/10/10). Each subject read and signed a written and an informed consent form prior to study enrollment.

The e-cigarettes provided to the subjects were of the same brand (NOBACCO e-cigarettes, black line) and of the same nicotine concentration. The e-cigarette itself was composed of a steel shell, a microprocessor powered by a lithium battery, a filter, and a removable (and renewable) cartridge. Three types of cartridges were available in the market for this e-cigarette, and we chose the medium one (NOBACCO MLB-MED filter), for which the manufacturer reports a measured dose of 11 mg of nicotine. Further information on the e-cigarette used in the current study can be found on the manufacturer's website.[13] Moreover, the e-cigarette cartridge selected for use in the experimental group has been analyzed for its chemical composition by the National Center for Scientific Research, Demokritos, in Greece.[14] According to their analysis, the cartridge contained propylene glycol (α-propylene glycol or 1,2-propanediol) in a concentration > 60%, linalool (3,7-dimethylocta-1,6-dien-3-ol) in a concentration < 5%, nicotine (< 10%), tobacco essence (< 5%), and methyl vanillin (4-hydroxy-3-methoxybenzaldehyde) at < 1%; no polyaromatic hydrocarbons were detected.[14]

Measurements were made in a sitting position with a nose clip using an Eco Medics AG CLD 88 Series chemiluminescence analyzer equipped with a Spiroware 3.0 software program. The patient was instructed to inhale as deeply as possible to total lung capacity through a filter mouthpiece and consecutively exhale at a mouth flow rate of 50 mL/s for 10 s. The exhalation rate was held steady by applying a constant positive pressure (10 cm H_2O) through a resistance factor while coaching the patient to exhale steadily using visual stimulation on the system screen. Three consecutive trials were performed with a 30-s interval. Results were measured in parts per billion (ppb).

Flows and lung volumes were measured in the sitting position, using a Jaeger MasterScreen spirometry system (heated pneumotach, resistance < 0.05 kPa/[L/s] at 10 L/s), with the highest FEV_1 recorded in line with pulmonary guidelines. Spirometry was measured according to the recommendations of the American Thoracic Society/European Respiratory Society task force guidelines.[15] FEV_1, FVC, FEV_1%, peak expiratory flow (PEF), and maximal expiratory flow (MEF) at 25%, 50%, and 75% of vital capacity were measured. Each maneuver was repeated for at least three technically acceptable forced expiratory flow curves. In order to attain the best results (the ones that represent the true status of the patient's respiratory system) from the basic pulmonary measurements (spirometry and dynamic lung volumes), the following criteria were established: (1) each measurement was repeated at least three times to confirm the proper collaboration of the patient and give the patient the chance to familiarize themselves with each process, and (2) the results of each measurement were reproducible (within 10% of the SD after three maneuvers).

The actual values of magnitude of respiratory impedance at 5 Hz (Z5Hz); respiratory resistance at 5, 10, and 20 Hz (R5Hz, R10Hz, and R20Hz, respectively); reactance at 5, 10, and 20 Hz; and resonant frequency were assessed with the use of an impulse oscillometry system (IOS). IOS is a noninvasive, easy examination that requires minimum, if any, compliance from the subject. During IOS measurements, a small loudspeaker creates a pulse-shaped pressure wave in front of the mouth, with alternate pulses (at different cycles per second [ie, 5 Hz, 10 Hz, 25 Hz]). The measurements were carried out according to the operating instructions provided by the manufacturer (Viasys Jaeger Masterscreen IOS system). After occluding the nose of the subject, he/she was instructed to breathe normally through a mouthpiece attached to the IOS system while seated. Among all the lung function tests, IOS measurements have one of the highest rates of reproducibility and sensitivity (as to detect even the earliest of pathophysiologic changes in the patient's pulmonary mechanics) and require the minimal physician subjectivity to obtain the correct measurement that corresponds to the patient's true pulmonary mechanical status.[16,17] Patients followed the instructions, and no discomfort or failure to comply was noticed. The whole maneuver lasted for 90 s and was repeated for verification. Results were measured in kPa /(L/s).

The Kolmogorov-Smirnov tests were applied to assess the normality of the data; all measurements were found to be normally distributed, with the exception of F_{ENO}. Pre vs post measurements, sex differences, and experimental vs control conditions were assessed through bivariate analyses. The paired Student *t* test was performed among parametric data, whereas nonparametric data were compared with the Wilcoxon signed rank test. Pearson correlations were applied to assess the correlations between the pre and post respiratory tests. Results are presented as means and 95% CIs. To control simultaneously for intervention group (experimental vs control) and baseline respiratory characteristics, additional linear regression analyses were performed; R^2 values, β coefficients, and 95% CI of the β are provided. The statistical analysis was performed with the statistical package PASW 18.0 (SPSS, Inc).

Results

The descriptive characteristics and baseline pulmonary functional status of participating subjects are depicted in Table 1. Differences in baseline respiratory function, IOS, or F_{ENO} were not identified when stratified by group (experimental vs control), whereas when stratified by sex, female participants were found to have a lower FEV_1, FVC, PEF, MEF at 50% of vital capacity, and MEF at 75% of vital capacity; however, baseline F_{ENO} concentrations and IOS measurements were not found to differ.

Table 1 —Baseline Characteristics and Respiratory Function of Study Participants by Sex

View Large | Save Table

Table 2 depicts the changes in F_{ENO} and respiratory mechanics before and after the use of an e-cigarette (experimental group) or a sham e-cigarette (control group). In all cases, the internal pre and post measurements per participant were highly correlated, whereas no differences between basic pulmonary measurements (data not shown) were identified between the two groups. In regard to pulmonary oxidative stress, our findings indicated that F_{ENO} within the experimental group decreased by 16% (by 2.14 ppb from 13.02 ppb to 10.89 ppb, $P = .005$) after the use of an e-cigarette, whereas F_{ENO} concentrations were not found to change within the control group (from 8.76 ppb to 8.75 ppb, $P = .859$). An additional sensitivity analysis among the 10 pairs of experimental group participants who also participated in the control group was performed and indicated a statistically significant decrease

in FENO, by 1.69 ppb (from 8.76 ppb to 7.07 ppb, $P = .002$), after using an e-cigarette. Using IOS as an indicator of pulmonary function among the study participants, airway impedance at Z5Hz increased in the experimental group by 0.033 kPa/(L/s) (95% CI, 0.016-0.050 kPa/[L/s], $P < .001$), whereas no differences were noted among control group participants (mean difference of −0.002 kPa/[L/s]; 95% CI, −0.010 to 0.006 kPa/[L/s]; $P = .591$). Correspondingly, lung resistance in the experimental group also increased at R5Hz, R10Hz, and R20Hz by an average of 0.031 kPa/(L/s) (95% CI, 0.014-0.048 kPa/[L/s]), 0.029 kPa/(L/s), (95% CI, 0.013-0.045 kPa/[L/s]), and 0.030 kPa/(L/s), (95% CI, 0.010-0.051 kPa/[L/s]), respectively. Moreover, peripheral pulmonary resistance also increased from 0.22 kPa/(L/s) to 0.25 kPa/(L/s) ($P = .05$). Similar statistical results to those previously mentioned were identified through the intergroup comparison (mean change in control vs mean change in experimental group) as seen in Table 2. Stratifying the experimental vs control group analysis by sex did not alter the direction or statistical association of the above findings. Pulmonary function assessed via spirometry did not change in either group (data not shown).

Table 2 —Baseline Characteristics by Group and Subsequent Intersubject and Intergroup Changes (Pre vs Post) in FENO and Flow Resistance (IOS) Following Use of an e-Cigarette

View Large | Save Table

Subsequently, a linear regression analysis was performed to assess the role of using an e-cigarette on the assessed respiratory outcomes, taking into account the baseline measurement of each participant and the group to which they were allocated. The key findings are depicted in Table 3, strengthening the results identified through the bivariate associations, as the changes noted in respiratory function were even greater once we controlled for the participants' baseline responses. It is noteworthy that peripheral flow resistance was found to increase approximately 18% after use of the e-cigarette (by 0.042 kPa/[L/s]), whereas flow resistance at R5Hz, R10Hz, and R20Hz increased by 0.040 kPa/(L/s), 0.034 kPa/(L/s), and 0.043 kPa/(L/s), respectively. Peripheral resistance overall increased by 0.042 kPa/(L/s) ($P = .024$), whereas a tendency for overall central airway resistance was noted; however, this difference was borderline nonstatistically significant (β, 0.034 kPa/[L/s]; 95% CI, −0.003 to 0.071; $P = .069$).

Table 3 —Regression Analysis on the Effect of Using an e-Cigarette on FENO and Airway Flow Resistance (IOS), Controlling for the Participants' Baseline Measurements

View Large | Save Table

Discussion

To our knowledge, this is the first study to find a physiologic response after inhaling from an e-cigarette. According to our findings, 5 min of use was sufficient to lead to an increase in lung flow resistance over a range of frequencies and was related to a decrease in FENO concentrations.

Impulse oscillometry as a methodologic approach has been used previously in clinical trials, can be used to diagnose obstructive lung disease, and has been shown to be superior to spirometry measurements during pulmonary assessment.[18-21] This is verified by the fact that e-cigarette usage was associated with increased flow resistance even though spirometry-assessed lung function was deemed normal, a finding corroborated by the fact that IOS can detect oncoming pathophysiologic changes of the respiratory system before spirometry.[20] Indeed, it has been demonstrated that changes in flow resistance precede changes in PEF and FEV_1 in experimentally induced airway obstruction, and it is possible that the changes we note in this study may indicate a similar preliminarily health effect.[21] We must state, however, that while the differences within our study are of statistical significance, the clinical changes may be too small to be of major clinical importance (ie, to induce dyspnea or breathing difficulties). However, these measurements were performed after only 5 min of ad lib e-cigarette use. A normal consumer would use the product likely several times a day; thus, the clinical impact might be greater. We hypothesize that the increase in peripheral flow resistance is attributable to the acute narrowing of the diameter of the peripheral airways, which could be due to either localized mucosal edema, smooth muscle contraction (and bronchospasm), or secretions. In the regression analysis, there was a tendency for central airway resistance to increase; however, this was borderline nonstatistically significant. It is possible that increasing the study's sample size might have increased the statistical significance, or we might hypothesize that using an e-cigarette may have a greater impact on peripheral rather than central airways.

A strong point of our findings was that e-cigarette use was associated with an immediate decrease in FENO concentrations. Nitric oxide is a gaseous mediator that has an important role in several physiologic processes in the respiratory tract, including vascular regulation, neurotransmission, host defense, and cytotoxicity.[22] Nitric oxide is an additional marker that has been implicated in the pathophysiology of airway diseases associated with smoking, is strongly correlated with eosinophilic inflammation and bronchial hyperreactivity, and has become an established marker for assessing oxidative stress, indicating the immediate effect e-cigarette usage might have on pulmonary homeostasis.[23-26]

As no standard definition of electronic nicotine delivery system exists, and as different manufacturers use different designs and incorporate a range of ingredients, there is limited evidence on the actual constituents of each brand. Although we identified the clinical changes in lung function due to electronic nicotine delivery system use, we can only hypothesize on the actual substances (or combination of substances) that could have caused the measured effect. One of the substances that was reported to be included in the e-cigarette we used was propylene glycol (other constituents included linalool, nicotine, tobacco essence, and methyl vanillin), and this could have played a role in the measured respiratory changes. Research has indicated that exposure to propylene glycol can induce respiratory irritation and increase the likelihood of developing asthma.[27,28] However, we cannot rule out the possibility that other constituents could be responsible or act in synergy with propylene glycol to induce the respiratory and oxidative responses that we noted.

This study has significant implications for product regulation and use and indicates a direction for further research. Our results were replicable and differed significantly in the bivariate analysis following exposure both within the experimental group (thus controlling for intersubject differences) and between groups (experimental vs control) and also in the regression analysis while controlling baseline characteristics. Controlling for baseline measurements allowed us to focus on the changes due to using the e-cigarette and not take into account underlying damage due to previous cigarette smoking or lung condition. The performed linear regression analysis furthermore allowed us to estimate the quantitative effects of using a single e-cigarette on mechanical and inflammatory measurable parameters. Moreover, the chemical composition of the cartridges used in e-cigarette be disclosed; knowledge of the contents enabled this study. However, despite these novel findings, our sample size remains relatively small, and further research is needed to investigate the mechanistic and toxicologic effects of long-term usage, which are potentially adverse and worthy of further investigation.

In conclusion, use of an e-cigarette for 5 min was found to cause an increase in impedance, peripheral airway flow resistance, and oxidative stress among healthy smokers. We must state, however, that although the differences within our study are of statistical significance, the clinical changes may be too small to be of major clinical importance. Notably, because these short-term effects were present even after only very limited usage, and a normal consumer would use the product most likely many times a day, it is possible that if e-cigarette use were a short-term bridge to smoking cessation, the long-term health benefits associated with their use might outweigh the short-term risks; however, this would need to be clarified. The FDA, as well as other international regulatory bodies, should pursue the regulation of the e-cigarette until manufacturers provide scientific evidence to support their claims. Additional research is warranted to obtain concrete evidence of an adverse health outcome.

Acknowledgments

Author contributions: Drs Vardavas and Behrakis take responsibility for the integrity of the data and accuracy of the data analysis.

Dr Vardavas: contributed to conception of the idea, data analysis, and manuscript preparation.

Dr Anagnostopoulos: contributed to performing laboratory measurements and helping draft the manuscript.

Dr Kougias: contributed to performing laboratory measurements and helping draft the manuscript.

Dr Evangelopoulou: contributed to performing laboratory measurements and helping draft the manuscript.

Dr Connolly: contributed to study design, data interpretation, and manuscript preparation.

Dr Behrakis: contributed to study supervision, study design, data interpretation, and manuscript preparation

Financial/nonfinancial disclosures: The authors have reported to *CHEST* that no potential conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

Role of sponsors: The sponsor had no role in the design of the study, the collection and analysis of the data, or in the preparation of the manuscript.

Abbreviations

e-cigarette	electronic cigarette
FDA	US Food and Drug Administration
FENO	fraction of exhaled nitric oxide
IOS	impulse oscillometry system
MEF	maximal expiratory flow
PEF	peak expiratory flow
ppb	parts per billion
R5Hz	airway resistance at 5 Hz
R10Hz	airway resistance at 10 Hz
R20Hz	airway resistance at 20 Hz
Z5Hz	airway impedance at 5 Hz

References

1 Cobb NK, Abrams DB. E-cigarette or drug-delivery device? Regulating novel nicotine products. *N Engl J Med.* 2011;3653:193-195. [CrossRef] [PubMed]

2 Noel JK, Rees VW, Connolly GN. Electronic cigarettes: a new 'tobacco' industry? *Tob Control.* 2011;201:81. [CrossRef] [PubMed]

3 Henningfield JE, Zaatari GS. Electronic nicotine delivery systems: emerging science foundation for policy. *Tob Control.* 2010;192:89-90. [CrossRef] [PubMed]

4 Flouris AD, Oikonomou DN. Electronic cigarettes: miracle or menace? *BMJ.* 2010;340:c311. [CrossRef] [PubMed]

5 FDAFDA Summary of results: laboratory analysis of electronic cigarettes conducted by FDA. US Department of Health and Human Services website.http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm. Accessed November 16, 2010.

6 Vansickel AR, Cobb CO, Weaver MF, Eissenberg TE. A clinical laboratory model for evaluating the acute effects of electronic "cigarettes": nicotine delivery profile and cardiovascular and subjective effects. *Cancer Epidemiol Biomarkers Prev.* 2010;198:1945-1953. [CrossRef] [PubMed]

7 Eissenberg T. Electronic nicotine delivery devices: ineffective nicotine delivery and craving suppression after acute administration. *Tob Control.* 2010;191:87-88. [CrossRef] [PubMed]

8 Etter JF. Electronic cigarettes: a survey of users. *BMC Public Health.* 2010;10:231. [CrossRef] [PubMed]

9 Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M. Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. *Tob Control.* 2010;192:98-103. [CrossRef] [PubMed]

10 Siegel MB, Tanwar KL, Wood KS. Electronic cigarettes as a smoking-cessation: tool results from an online survey. *Am J Prev Med.* 2011;404:472-475. [CrossRef] [PubMed]

11 Karrasch S, Ernst K, Behr J, et al; KORA Study Group KORA Study Group Exhaled nitric oxide and influencing factors in a random population sample. *Respir Med.* 2011;1055:713-718. [CrossRef] [PubMed]

12 Mauer MP, Cummings KR. Impulse oscillometry and respiratory symptoms in World Trade Center responders, 6 years post-9/11. *Lung.* 2010;1882:107-113. [CrossRef] [PubMed]

13 NOBACCO website. http://www.nobacco.gr/category.asp?catid=467. Accessed February 24, 2011.

14 Leondiadis L. Results of chemical analyses in NOBACCO electronic cigarette refills. 2009; Athens, Greece Mass Spectrometry and Dioxin Analysis Laboratory, National Centre for Scientific Research ("Demokritos"

15 Miller MR, Hankinson J, Brusasco V, et al; ATS/ERS Task Force ATS/ERS Task Force Standardisation of spirometry. *Eur Respir J.* 2005;262:319-338. [CrossRef] [PubMed]

16 Blonshine S, Goldman MD. Optimizing performance of respiratory airflow resistance measurements. *Chest.* 2008;1346:1304-1309. [CrossRef] [PubMed]

17 Goldman MD, Carter R, Klein R, Fritz G, Carter B, Pachucki P. Within- and between-day variability of respiratory impedance, using impulse oscillometry in adolescent asthmatics. *Pediatr Pulmonol.* 2002;344:312-319. [CrossRef] [PubMed]

18 Al-Mutairi SS, Sharma PN, Al-Alawi A, Al-Deen JS. Impulse oscillometry: an alternative modality to the conventional pulmonary function test to categorise obstructive pulmonary disorders. *Clin Exp Med.* 2007;72:56-64. [CrossRef] [PubMed]

19 Borrill ZL, Houghton CM, Tal-Singer R, et al. The use of plethysmography and oscillometry to compare long-acting bronchodilators in patients with COPD. *Br J Clin Pharmacol.* 2008;652:244-252. [CrossRef] [PubMed]

20 Kanda S, Fujimoto K, Komatsu Y, Yasuo M, Hanaoka M, Kubo K. Evaluation of respiratory impedance in asthma and COPD by an impulse oscillation system. *Intern Med.* 2010;491:23-30. [CrossRef] [PubMed]

21 Vink GR, Arets HG, van der Laag J, van der Ent CK. Impulse oscillometry: a measure for airway obstruction. *Pediatr Pulmonol.* 2003;353:214-219. [CrossRef] [PubMed]

22 Moncada S, Palmer RMJ, Higgs EA. Nitric oxide: physiology, pathophysiology, and pharmacology. *Pharmacol Rev.* 1991;432:109-142. [PubMed]

23 Kharitonov SA, Robbins RA, Yates D, Keatings V, Barnes PJ. Acute and chronic effects of cigarette smoking on exhaled nitric oxide. *Am J Respir Crit Care Med.* 1995;1522:609-612. [PubMed]

24 Rytilä P, Rehn T, Ilumets H, et al. Increased oxidative stress in asymptomatic current chronic smokers and GOLD stage 0 COPD. *Respir Res.* 2006;7:69. [CrossRef] [PubMed]

25 Hoyt JC, Robbins RA, Habib M, et al. Cigarette smoke decreases inducible nitric oxide synthase in lung epithelial cells. *Exp Lung Res.* 2003;291:17-28. [CrossRef] [PubMed]

26 American Thoracic Society WorkshopAmerican Thoracic Society Workshop ATS Workshop Proceedings: Exhaled nitric oxide and nitric oxide oxidative metabolism in exhaled breath condensate: Executive summary. *Am J Respir Crit Care Med.* 2006;1737:811-813. [CrossRef] [PubMed]

27 Wieslander G, Norbäck D, Lindgren T. Experimental exposure to propylene glycol mist in aviation emergency training: acute ocular and respiratory effects. *Occup Environ Med.* 2001;5810:649-655. [CrossRef] [PubMed]

28 Choi H, Schmidbauer N, Sundell J, Hasselgren M, Spengler J, Bornehag CG. Common household chemicals and the allergy risks in pre-school age children. *PLoS ONE.* 2010;510:e13423. [CrossRef] [PubMed]

JACC Vol. 29, No. 7
June 1997:1422–31

Cardiovascular Toxicity of Nicotine: Implications for Nicotine Replacement Therapy

NEAL L. BENOWITZ, MD, STEVEN G. GOURLAY, MB, BS, PHD

San Francisco, California

This review discusses the known cardiovascular effects of smoking and the effects of nicotine without tobacco smoke and interprets the available data on cardiovascular risk during nicotine replacement therapy (NRT). Nicotine gum and patches are now approved for over the counter sale in the United States. Smokers with cardiovascular disease are advised to seek physician counseling before using nicotine products, but information regarding the safety of these products in such patients is not readily available to most physicians. Nicotine may contribute to cardiovascular disease, presumably by hemodynamic consequences of sympathetic neural stimulation and systemic catecholamine release. However, there are many potential cardiovascular toxins in cigarette smoke other than nicotine. The doses of nicotine obtained by regular cigarette smoking generally exceed those delivered by NRTs, and the cardiovascular effects of nicotine are, in general, more intense when delivered rapidly by cigarette smoking than the slower delivery by transdermal nicotine or nicotine gum. Because the dose–cardiovascular response relation for nicotine is flat, the effects of cigarette smoking in conjunction with NRT are similar to those of cigarette smoking alone. Cigarette smoking increases blood coagulability, a major risk factor for acute cardiovascular events, whereas transdermal nicotine does not appear to do so. Clinical trials of NRT in patients with underlying, stable coronary disease suggest that nicotine does not increase cardiovascular risk. At worst, the risks of NRT are no more than those of cigarette smoking. The risks of NRT for smokers, even for those with underlying cardiovascular disease, are small and are substantially outweighed by the potential benefits of smoking cessation.

(J Am Coll Cardiol 1997;29:1422–31)

Nicotine gum and patches are now approved for over the counter sale in the United States. The package inserts advise smokers with cardiovascular disease to seek physician counseling before using the products, but information on the safety of nicotine in the setting of cardiovascular disease is not readily available to most physicians.

Cigarette smoking is well known to increase the risk of cardiovascular disease. Nicotine affects cardiovascular function and could contribute to cardiovascular disease. Of concern is whether nicotine medications pose a cardiovascular risk, and, if so, how does this risk compare to that of cigarette smoking? The risk–benefit analysis for nicotine medication in patients with active or silent heart disease is important both in helping to make decisions on rational therapy for smoking cessation and for other potential indications for nicotine therapy, such as ulcerative colitis.

Cigarette smoking accelerates atherosclerosis, producing premature atherosclerosis at epicardial coronary arteries, the aorta, the carotid and cerebral arteries and large arteries in the peripheral circulation (1,2). Smoking is also associated with an increased risk of acute cardiovascular events, including acute myocardial infarction, sudden death and stroke. Other effects include aggravation of stable angina pectoris, intermittent claudication and vasospastic angina, rethrombosis after thrombolysis and restenosis after angioplasty (3–7).

The acute cardiovascular effects of nicotine are of primary concern with respect to clinically relevant risks of nicotine replacement therapy (NRT) because of their potentially serious nature. There have been anecdotal reports of acute myocardial infarction and stroke in patients taking NRT, with or without simultaneous cigarette smoking (Table 1). The possible contribution of nicotine to acute cardiovascular events is the major focus of this review.

Smoking-related atherosclerosis is not necessarily an effect of nicotine (1,2). It is important to recognize that cigarette smoke is a complex mixture of chemicals that includes not only nicotine but also potentially cardiotoxic substances, such as carbon monoxide, oxidant gases and polycyclic aromatic hydrocarbons. The role of nicotine, if any, in causing acute or chronic cardiovascular disease has not been definitely demon-

From the Clinical Pharmacology Unit, Medical Service, San Francisco General Hospital Medical Center and Departments of Medicine, Psychiatry and Pharmacy, University of California San Francisco, San Francisco, California. This work was supported by Grants DA02277 and DA01696 from the National Institute on Drug Abuse and by NIH Grant RR-00083 from the Division of Research Resources, National Institutes of Health, Bethesda, Maryland; by an Overseas Research Fellowship from the National Heart Foundation of Australia, Canberra; and by Alza Corporation, Palo Alto, California.

All editorial decisions for this article, including selection of referees, were made by a Guest Editor. This policy applies to all articles with authors from the University of California San Francisco.

Manuscript received October 24, 1996; revised manuscript received February 24, 1996, accepted March 3, 1997.

Address for correspondence: Dr. Neal L. Benowitz, University of California San Francisco, Box 1220, San Francisco, California 94143-1220. E-mail: nbeno@itsa.ucsf.edu.

Published by Elsevier Science Inc.

0735-1097/97/$17.00
PII S0735-1097(97)00079-X

Abbreviations and Acronyms

CGRP = calcitonin growth-related peptide
ECG = electrocardiographic
HDL = high density lipoprotein
LDL = low density lipoprotein
NO = nitric oxide
NRT = nicotine replacement therapy
VLDL = very low density lipoprotein

strated. If nicotine contributes to smoking-related atherosclerosis, it is unlikely to be of clinical importance during the relatively brief duration of NRT for smoking cessation.

Mechanisms by Which Cigarette Smoking Contributes to Acute Vascular Events

Mechanisms by which cigarette smoking is likely to contribute to acute vascular events include 1) induction of a hypercoagulable state; 2) increased myocardial work; 3) carbon monoxide–mediated reduced oxygen-carrying capacity of the blood; 4) coronary vasoconstriction; and 5) catecholamine release.

Hypercoagulable state. Several lines of evidence suggest that cigarette smoking–mediated thrombosis is a major factor in acute vascular events. Epidemiologic studies (2) indicate that cigarette smoking increases the risk of acute myocardial infarction and sudden death much more than it increases the risk of angina pectoris. The former are believed to be mediated by thrombosis, the latter primarily by hemodynamic factors. Recent research with thrombolysis supports this concept. The prognosis in patients with myocardial infarction after treatment with thrombolysis is better in smokers than in nonsmokers (8). Smokers, at the time of myocardial infarction, were younger, had fewer cardiac risk factors and had less severe underlying coronary disease than did nonsmokers. Enhanced thrombosis superimposed on less severely stenotic arteries best explains these observations. Observations that smokers who continue to smoke after thrombolysis or angioplasty have substantially increased risk of reinfarction or reocclusion support the idea that thrombosis is a major mechanism of smoking-related events (5,7).

Increased myocardial work. Although surveys of outpatient blood pressure measurement report that smokers have a lower blood pressure than matched nonsmokers (9), more recent studies of ambulatory blood pressure monitoring show that long-term cigarette smoking increases average heart rate and blood pressure throughout the day (10,11). In addition, each cigarette transiently increases heart rate and blood pressure (12). Cigarette smoking causes an acute increase in the stiffness of large peripheral arteries (13,14). Cigarette smoking also increases myocardial contractility (15,16). Thus, myocardial work is increased. When myocardial blood flow increases, coronary blood flow must increase to provide necessary oxygen and nutrients. Where coronary blood flow is limited, the blood flow requirements of the heart may not be able to be met, resulting in ischemia.

Table 1. Summary of Published Adverse Cardiovascular Events in People Using Nicotine Replacement Therapy

Age (yr)/Gender	Underlying Cardiovascular Disease	Type and Dose of Nicotine Product	Time of Onset of Event	Concurrent Cigarette Smoking
AF (109–111)				
52/M	Coronary disease, Hx and paroxysmal AF	2-mg gum	5 min after 1st piece of gum, day 3 of use	Unknown
35/M	None known	2-mg gum, 30 pieces/day	At night during sleep, after 2-mo use	Unknown
55/F	None known	21-mg patch	5 h after applying patch	Yes
MI (112–114)				
34/M	Normal CAs, except for thrombosed LAD	21-mg patch	Angina began several hours after 1st patch; MI 10 AM, day 14	Yes
47/M	Recent MI with 50% LAD stenosis	21-mg patch	While smoking 1st cigarette and wearing patch, day 7	Yes
39/M	Normal coronary angiogram	21-mg patch	Several hours after application of patch, day 20	No
69/F	Unknown	44-mg patch	Day 25	Unknown
Cerebral isch (114–116)				
40/M	Internal carotid aneurysm clipped, persistent cerebral artery spasm	One 10-mg patch	4 h after 1st patch application, postoperative day 8	Yes
43/F	Unknown	44-mg patch	Day 3	Unknown
70/F	Unknown	22-mg patch	Day 11 of 22-mg patch, after 4 wk of 44-mg patch	Unknown
62/F	None known	21-mg patch	Day 21	Unknown

Numbers in parentheses are reference numbers. AF = atrial fibrillation; CAs = coronary arteries; F = female; Hx = hypertension; isch = ischemia; LAD = left anterior descending coronary artery; M = male; MI = myocardial infarction.

JACC Vol. 29, No. 7
June 1997:1422–31

Carbon monoxide effects on oxygen delivery. Smokers inhale carbon monoxide in cigarette smoke, and carboxyhemoglobin levels average ~5%, but may be ≥10%. This compares to levels of 0.5% to 2% in nonsmokers, depending on their exposure to automobile exhaust. Carbon monoxide binds to hemoglobin, reducing both the amount of hemoglobin available to carry oxygen and also impeding oxygen release by hemoglobin that is not directly binding carbon monoxide (17). In experimental studies, inhalation of carbon monoxide at levels comparable to those found in cigarette smokers has been shown (18–20) to reduce exercise tolerance in patients with angina pectoris, intermittent claudication and chronic obstructive lung disease. Carbon monoxide exposure in people with obstructive coronary disease also results in a greater degree of exercise-induced ventricular dysfunction, as well as an increased number and complexity of ventricular arrhythmias during exercise (21,22). Carbon monoxide inhalation reduces the ventricular fibrillation threshold in animals and may contribute to atherogenesis (23,24).

Coronary vasoconstriction. Coronary vasoconstriction reduces myocardial blood supply and could produce ischemia or arrhythmias. Cigarette smoking increases coronary blood flow, associated with a small decrease in coronary vascular resistance, in people with normal coronary arteries, presumably a response to increased myocardial work and the need for additional blood supply (25). However, in people with obstructive coronary disease, cigarette smoking results in a lesser increase, no change or even a decrease in coronary blood flow, depending on the severity of the underlying coronary disease (25,26). In these patients, cigarette smoking increases coronary vascular resistance, consistent with coronary vasoconstriction. Cigarette smoking is associated with increased risk of vasospastic angina and a poor response to medications in patients who have vasospastic angina (27,28). Cigarette smoking has been observed to acutely produce vasospasm during angiography (6).

Pretreatment with calcium channel blocking agents or nitroglycerin results in an increase in coronary blood flow after cigarette smoking in patients with coronary artery disease who had no increase after cigarette smoking alone, further supporting the idea that cigarette smoking normally results in coronary vasoconstriction (29). Recently, intracoronary Doppler measurements have demonstrated (30) that cigarette smoking constricts epicardial arteries as well as increases total coronary vascular resistance. Thus, the impairment of coronary blood flow by cigarette smoking appears to result from constriction of both epicardial and resistance blood vessels.

Catecholamine release. Cigarette smoking acutely increases plasma levels of norepinephrine and epinephrine and increases 24-h urinary excretion of these catecholamines (31,32). The effects of cigarette smoking on coronary blood flow appear to be catecholamine mediated because the increase in coronary vascular resistance is blocked by alpha-adrenoceptor blocking agents (33). In addition to mediating the hemodynamic effects of cigarette smoking, catecholamines could contribute to arrhythmogenesis. For example, acute ischemia combined with smoking-related catecholamine release could result in a greater risk of sustained and potentially fatal tachyarrhythmias. Cigarette smoking has been shown (34) to accelerate atrioventricular node conduction, which could contribute to supraventricular arrhythmias. Catecholamine release has been speculated to account for the greater risk of sudden death in smokers than in nonsmokers (35).

Mechanisms by Which Cigarette Smoking May Promote Atherosclerosis

Cigarette smoking could accelerate atherosclerosis by a variety of mechanisms. Some of those more prominently mentioned include 1) adverse effects on lipids; 2) producing endothelial damage or dysfunction, or both; 3) hemodynamic stress; 4) oxidant injury; 5) neutrophil activation; 6) enhanced thrombosis; and 7) increased fibrinogen and blood viscosity.

Effects of cigarette smoking on lipids. Smokers on average have a higher risk lipid profile than do nonsmokers. Levels of very low density lipoprotein (VLDL) are higher; high density lipoprotein (HDL) cholesterol levels (primarily HDL-2) are lower; triglycerides are higher; and apoprotein A1 levels are perhaps lower in smokers than in nonsmokers (36,37). There is also some evidence (38) that smokers have higher levels of oxidized low density lipoprotein (LDL), which is believed to promote atherogenesis. Oxidized LDL is taken up preferentially by macrophages, which become the foam cells that are an integral part of the atherosclerotic plaque. These abnormalities in the blood lipid profile appear to reverse, at least in part, within 2 weeks of smoking cessation (39).

Endothelial toxicity. Endothelial damage is thought to be an initiating event in atherosclerosis. There is evidence that cigarette smoking produces endothelial damage (40). For example, endothelial changes have been described in the umbilical artery of babies of smoking mothers (41). Endothelial changes included swelling, blebbing and contraction, with resultant opening of endothelial junctions and formation of subendothelial edema.

Cigarette smoking is associated with impaired flow-mediated, endothelium-dependent peripheral arterial vasodilation, an effect that is at least partly reversible after smoking cessation (42). Smokers without atherosclerosis have coronary vasoconstrictor responses to acetylcholine, which in the presence of endothelial cell function normally produces vasodilation (43). Impaired arterial vasodilation in smokers appears to be a consequence of impaired release of endothelium-derived relaxing factor (believed to be nitric oxide [NO]) (44,45). Normal NO release has potentially beneficial cardiovascular effects in mediating acetylcholine-induced coronary vasodilation and inhibiting platelet aggregation, smooth muscle cell proliferation and adhesion of monocytes to the endothelium. Impaired release of NO in cigarette smokers could contribute to acute cardiovascular events and to accelerated atherogenesis.

Hemodynamic stress may contribute to endothelial dam-

age, as occurs in chronic hypertension. As discussed, regular smoking increases daytime blood pressure, blood pressure variability and heart rate. Persistent heart rate elevation has been shown (46) in primates on an atherogenic diet to accelerate atherosclerosis. Thus, hemodynamic effects of cigarette smoking would be expected to result in more turbulent blood flow and could contribute to endothelial damage.

Oxidant injury. Cigarette smoke contains many oxidant gases. Reduced plasma levels of the antioxidant glutathione and increased levels of lipid peroxidation products have been measured in the plasma of smokers, reflecting the oxidant stress of cigarette smoke (47,48). As noted previously, cigarette smoking is believed to be associated with oxidation of LDL, which may promote atherosclerosis (38). Oxidant substances in cigarette smoke appear to be responsible for endothelial dysfunction. Antioxidants such as vitamin C reverse the impairment in endothelium-mediated vasodilation in smokers (49).

Neutrophil activation. Cigarette smoking is consistently associated with increased circulating neutrophil counts (50). Neutrophil counts decline rapidly after cessation of cigarette smoking (51). An elevated neutrophil count is a risk factor for coronary events (52). Neutrophils may contribute to ischemic heart disease through release of oxygen-derived free radicals, proteases and leukotrienes (53). These mediators can result in endothelial cell injury and aggregation and activation of platelets, which in turn can aggravate coronary ischemia.

Enhanced thrombosis. Cigarette smoking produces a hypercoagulable state, associated with platelet activation and possibly other changes in clotting factors (54). Enhanced viscosity is contributed to by increased fibrinogen levels and increased red cell mass in cigarette smokers (55). Hypercoagulability may contribute to atherosclerosis, presumably by release of platelet factors that promote smooth muscle cell migration and other effects that promote atherosclerosis (56).

Fibrinogen and blood viscosity. Increased fibrinogen is one of the strongest predictors of coronary events (57). Cigarette smoking increases fibrinogen levels, although the mechanism is unclear. Smokers also have elevated red blood cell mass, as a response to long-term carbon monoxide exposure (58). Carbon monoxide reduces oxygen-carrying capacity, resulting in a state of relative hypoxemia. In response, red blood cell masses increase, allowing more oxygen to be carried to body organs. Both increased fibrinogen and increased red blood cell mass increase blood viscosity, which is believed to contribute to platelet activation, which, as discussed, promotes atherogenesis. Fibrinogen may also contribute to atherosclerosis through direct activation of platelets, acting on specific platelet receptors (57).

Cardiovascular Pharmacology of Nicotine

Thus far, the discussion has focused on the cardiovascular effects of cigarette smoking. At this point, the focus will be the known effects of nicotine itself.

Nicotine binds to nicotinic cholinergic receptors, which are located in the brain, autonomic ganglia, the adrenals and neuromuscular junction (59). The main cardiovascular effect of nicotine is sympathetic neural stimulation. Sympathomimetic effects are mediated by several mechanisms. Central nervous system–mediated sympathetic stimulation can occur through activation of peripheral chemoreceptors, direct effects on the brain stem and effects on more caudal portions of the spinal cord. Intrapulmonary chemoreceptors may also contribute to brain-mediated sympathetic arousal. The site that appears to be most sensitive to low levels of nicotine is the carotid chemoreceptor. Peripheral mechanisms include catecholamine release from the adrenals and direct release or enhancement of release of catecholamines from vascular nerve endings.

Nicotine works primarily by enhancing the release of various neurotransmitters, including epinephrine, norepinephrine, dopamine, acetylcholine, serotonin, vasopressin, glutamate, NO (60), calcitonin growth-related peptide (CGRP) (60) and beta-endorphin. Thus, in addition to catecholamine-mediated actions, some other of these effects, such as acetylcholine, serotonin, NO, CGRP or vasopressin release, may contribute to effects of nicotine on blood vessels.

Salient observations on the pharmacokinetics and pharmacodynamics of nicotine most relevant to cardiovascular safety are summarized in Table 2. More detail is available in comprehensive reviews of the pharmacology of nicotine (59,61).

Acute Cardiovascular Effects of Nicotine

Hemodynamic actions of nicotine. The hemodynamic effects of cigarette smoking appear to be mediated by nicotine. Intravenous nicotine, nicotine nasal spray and nicotine chewing gum all acutely increase heart rate up to 10 to 15 beats/min and increase blood pressure up to 5 to 10 mm Hg, responses similar to the effects of cigarette smoking (62–64). Transdermal nicotine appears to cause lesser acute hemodynamic changes than smoking (32).

Nicotine increases cardiac output by increasing both heart rate and myocardial contractility. Nicotine gum chewing has been shown to aggravate regional myocardial hypoperfusion in patients with known coronary artery disease (65). Nicotine constricts some vascular beds, such as the skin. Cutaneous vasoconstriction explains the reduction in fingertip skin temperature that is seen with administration of nicotine (63). There is evidence that cutaneous vasoconstriction is modulated at least in part by release of vasopressin because the effect was inhibited by administration of a vasopressin antagonist (66). Nicotine appears to dilate other vascular beds, such as skeletal muscle (67,68). Skeletal muscle vasodilation may in part be a result of the increase in cardiac output, although animal studies suggest that release of epinephrine from nerve terminals may also contribute (13).

In anesthetized dogs, coronary blood flow has a biphasic response to nicotine. Initially, blood flow increases, in the large coronary vessels as well as in the smaller resistance vessels, believed to be a result of increased myocardial metabolic demand. Secondarily, there is a decrease in blood flow that

Table 2. Pharmacokinetic and Pharmacodynamic Considerations Concerning Cardiovascular Safety of Nicotine

Nicotine from cigarette smoke is absorbed rapidly and results in arterial plasma concentrations in body organs 6–10 times higher than venous plasma concentrations (117). Slower delivery systems, such as nicotine gum or patch, will produce much lower peak arterial concentrations
When smokers involved in most treatment trials are considered, the level of nicotine produced and the daily dose of nicotine delivered by standard doses of NRT are less than that typically taken in from cigarette smoking (118–122)
When people using NRT to quit smoking continue to smoke, the resulting plasma nicotine concentrations are not likely to be much greater than those observed before attempting to quit. Only modest increases in plasma nicotine concentration are observed when transdermal nicotine is combined with usual smoking (108)
Because of rapid delivery of high concentrations of nicotine, with minimal time for development of tolerance, cigarette smoking results in more intense acute cardiovascular effects than the same dose of nicotine absorbed from NRT (123)
Cigarette smoking and transdermal nicotine appear to have similar overall hemodynamic effects; however, cigarette smoking activates coagulation and increases 24-h epinephrine excretion, whereas transdermal nicotine does not (32)
The cardiovascular dose–response relation for nicotine is relatively flat; that is, after a threshold effect, nicotine produces little more effect despite higher blood levels (106)
Combining cigarette smoking with nicotine administered by other routes appears to have cardiovascular effects similar to cigarette smoking alone (107); thus, smoking while using nicotine-reduced therapy would not be expected to have additional effects but would produce the same effects as smoking alone

Numbers in parentheses are reference numbers. NRT = nicotine replacement therapy.

appears to be mediated by alpha-adrenergic vasoconstriction of coronary resistance vessels (69,70). As described previously, cigarette smoking may constrict coronary arteries, presumed due to nicotine-mediated catecholamine release. Of note, the chewing of 4 mg of nicotine gum by healthy nonsmokers has also been shown (70) to blunt the increase in coronary blood flow that occurs with an increase in heart rate, produced either by nicotine or cardiac pacing. This finding confirms that nicotine is capable of constricting coronary arteries even at low doses in humans.

Nicotine has been shown (71) to worsen myocardial dysfunction in regionally "stunned," ischemic myocardium of anesthetized dogs. In a placebo-controlled experiment, transient ischemia was induced in dogs by 15 min of left anterior descending coronary artery clamping. Segmental shortening recovered to only 29% of the preischemic baseline in nicotine-pretreated animals (80 μg/kg body weight intravenously over 15 min) compared with 54% for saline-treated control dogs ($p < 0.01$). The dose of nicotine did not alter heart rate, blood pressure or blood flow or cause myocyte necrosis.

Nicotine and platelet function. There has been considerable research into the effects of nicotine on platelet function. Nicotine appears not to have a significant direct effect on platelets in vitro, at least at concentrations relevant to human smoking (72). Studies of long-term nicotine administration in rodents do not show increased platelet activity; rather, they show reduced platelet aggregability (73). However, in a study in dogs with partially occluded coronary arteries (74), intravenous nicotine increased the frequency and severity of phasic reductions in blood flow, an effect that indicates platelet aggregation. The effects of nicotine on phasic blood flow were blocked by phentolamine, an alpha-adrenergic blocker, consistent with the idea that catecholamine release mediates the effects. Unfortunately, the study is not readily generalizable to human smoking because the dogs were naive (nontolerant) to nicotine, and the dose (80 μg/kg over 3 to 5 min) was large (equivalent to a human smoking approximately five cigarettes in 5 min).

Platelet studies in human smokers yield conflicting results and are difficult to interpret because cigarette smoke contains many other factors besides nicotine that could promote platelet aggregation. Studies of nicotine gum and transdermal nicotine do not show evidence of platelet activation (32,75).

Also of potential importance in assessing the role of nicotine in platelet activation are studies of urinary thromboxane A_2 metabolite excretion in tobacco snuff users (76). Thromboxane A_2 is released from platelets when they aggregate, and excretion of thromboxane A_2 metabolites reflects in vivo platelet activation. Snuff users have long-term exposure to levels of nicotine comparable to those experienced by cigarette smokers but are not exposed to tobacco combustion products. Snuff users had no evidence of platelet activation. Thromboxane A_2 metabolite excretion rates in snuff users were similar to those who did not use tobacco and lower than those of cigarette smokers (who are known to have activated platelets), suggesting that nicotine itself is not responsible for platelet activation.

Nicotine and prostaglandins. Nicotine can inhibit the in vitro synthesis of prostacyclin in isolated blood vessels and isolated hearts (77,78). Prostacyclin is thought to be important in vascular homeostasis in that it is a local vasodilator and has antiplatelet aggregation effects. It has been speculated that nicotine could produce an imbalance between the vasodilating antiplatelet prostacyclin and the vasoconstricting platelet-aggregating thromboxane A_2, the latter of which is released from platelets. One early study (79) in smokers using radioimmunoassay of urinary eicosanoid metabolites supported the idea that nicotine might inhibit prostacyclin synthesis. However, more recent studies (80–82) using gas chromatographic–mass spectrometric specific assays for urinary prostacyclin metabolites have found no evidence that cigarette smoking is associated with reduced release of prostacyclin. In contrast,

prostacyclin metabolite excretion increased, suggesting stimulation of endothelial activity. Smokeless tobacco users, who have high systemic levels of nicotine, do not have increased prostacyclin metabolite excretion compared with people who use no tobacco. Thus, there is no convincing evidence that nicotine affects prostacyclin synthesis or release in people.

Chronic Cardiovascular Effects of Nicotine

Long-term atherosclerosis experiments. An increased rate of development of aortic (83) and carotid (84) atherosclerosis during nicotine treatment of cholesterol-fed rabbits has been observed. Although these two studies suggest that nicotine may be atherogenic in the presence of hypercholesterolemia, the rabbit atherosclerosis models used are not readily generalizable to humans: 1) The plasma concentrations of cholesterol produced were severalfold greater than those usually seen in hypercholesterolemic humans, and there may be a threshold below which a synergistic effect of nicotine and hypercholesterolemia is no longer clinically relevant. 2) High per-kilogram doses of nicotine were used in one study (11 mg/kg per day) (84), and plasma concentrations were not measured in either study. Another study (85) used a lower dose of nicotine (1 mg/kg per day) and a 2% cholesterol diet and failed to demonstrate increased atherosclerosis.

Nicotine and endothelial cell injury. Nicotine at concentrations similar to those of cigarette smokers modulates the structural and functional characteristics of cultured vascular smooth muscle and endothelial cells (86,87). Animal studies (88–90) support the idea that nicotine can produce endothelial cell injury, although the mechanism is not clear. Oral nicotine administered to rats to achieve blood levels comparable to those in human smokers produced greater myointimal thickening of the aorta after experimental injury (denudation of the endothelium with a balloon catheter) than that in control animals (91). The excessive myointimal thickening in nicotine-treated animals is consistent with a response to persistent injury to endothelial cells. In support of the relevance of animal or in vitro studies to the effects of nicotine in humans, Davis et al. (92) reported an increase in the number of endothelial cells found in venous blood (reflecting endothelial injury) and a decrease in platelet aggregate ratios (reflecting platelet aggregation) in nonsmokers who smoked tobacco but not nontobacco cigarettes.

Nicotine and lipids. Nicotine, by release of catecholamines, induces lipolysis and releases plasma free fatty acids. There is evidence that these free fatty acids are primarily taken up by the liver, which might be expected to increase the synthesis of VLDL, consistent with changes described in cigarette smokers (93).

Results of studies of the effects of nicotine on lipids in animals are conflicting. Injection of nicotine or feeding of nicotine has been reported (83,84,88) to increase total cholesterol in rabbits and monkeys receiving a high cholesterol diet. Nicotine feeding in squirrel monkeys for 2 years has been shown (94) to increase plasma levels of LDL. The mechanism in monkeys included both accelerated synthesis of LDL through lipolysis of HDL and VLDL and impaired clearance of LDL. Of importance in interpreting these animal studies is that high doses of nicotine have been administered, often by an oral route, and without measurement of blood levels of nicotine to determine exposure adequately.

Most studies in humans given nicotine preparations suggest that nicotine delivered in these forms does not have an adverse effect on lipid profiles. In one study (95), nicotine chewing gum (2 mg eight times a day) was given to healthy nonsmokers for 2 weeks. No changes in plasma concentrations of triglycerides; total, HDL or LDL cholesterol; or apolipoprotein A1 or B were noted. In another study (96), 20 nonsmokers with ulcerative colitis received transdermal nicotine (15 mg/day) for 12 weeks. No changes in plasma lipids were found. Also, there were no changes in white cell count or platelet activation (assessed by platelet volume and expression of P-selectin), and no evidence of endothelial damage (assessed by plasma Von Willebrand factor antigen levels) was detected. Data from smokers who stop smoking and use transdermal nicotine indicate that lipids change toward normal while taking nicotine (97).

Nicotine Replacement in Patients With Cardiovascular Disease

In this section, evidence from cardiovascular adverse event reports and from clinical trials of NRT is examined.

Case reports of adverse cardiovascular events. In view of the known adverse effects of cigarette smoking and the current understanding of the pharmacology of nicotine, as reviewed previously, it is to be expected that acute cardiovascular events occurring in people using nicotine medications would raise concern. Accordingly, there are scattered published reports linking nicotine replacement therapies to acute cardiovascular events. Acute myocardial infarction in five patients who were smoking cigarettes while using nicotine patches has been reported in the press (98). Full details of these cases have not been published, but they were carefully reviewed by a Food and Drug Administration (FDA) advisory committee and judged not to be causally related to nicotine (99). Published case reports of adverse cardiovascular events are summarized in Table 1. Postmarketing surveillance data (New Drug Application Supplement) have shown only isolated and sporadic cardiovascular events, with no consistent relationship to the NRT.*

Establishing whether the relation between NRT and cardiovascular events is causal is difficult. Acute cardiovascular events are common in cigarette smokers, and the increased risk for such events persists beyond the time when they stop smoking. Therefore, it is impossible to ascertain from retro-

*Marion Merrell Dow (Hoechst Marion Roussel), NDA 18-612, NDA 20-066, Summary of Safety Information, Vol. 1, 19–48, August 20, 1993; Alza Corporation NDA 20-165, Integrated Summary of Safety Data, Vols. 11.51–11.55, August 7, 1995.

spective reports whether acute cardiovascular events reflect the risk of underlying disease, cigarette smoking, concurrent cigarette smoking or nicotine medications, alone or in combination. Smokers and ex-smokers are at increased risk for acute myocardial infarction, and a higher than average number of infarctions would be expected in the general population of people trying to quit smoking, with or without the use of NRT to aid smoking cessation.

Because of the relative infrequency of the cardiovascular events of concern, the number of subjects in a formal study needs to be quite large. One large source of observational data is the Lung Health Study cohort, in which 5,887 middle-aged smokers with chronic obstructive pulmonary disease were followed up for 5 years. During that study (100), two-thirds of the subjects were provided with smoking cessation therapy, including nicotine gum. Many of these subjects used nicotine gum heavily for several years. A comparison of smokers versus quitters with nicotine gum versus quitters without nicotine gum showed no increase in hospital admissions for cardiovascular events with nicotine gum treatment (101). In fact, the opposite was observed. Study participants who quit smoking and used nicotine gum had a lower hospital admission rate for cardiovascular disease than participants who quit smoking and did not use gum. Hospital admission rates were similar among subjects who failed to quit smoking, with or without nicotine gum use. In considering these results, it should be remembered that nicotine treatment was not randomly assigned, and therefore the usual caveats regarding sources of bias from comparisons of subgroups must be applied. For example, some participants motivated to use nicotine gum may have had a lower cardiovascular risk to begin with. Nevertheless, the data strongly suggest that nicotine gum use did not increase the rate of hospital admissions for cardiovascular disease.

Clinical trials of NRT in patients with cardiovascular disease. The results of two controlled trials of NRT in patients with cardiovascular disease have been published (102,103). The first study was a 5-week, placebo-controlled trial of 14 to 21 mg/day of transdermal nicotine in 156 patients with stable coronary artery disease (102). Cardiac symptoms were recorded, and in a subgroup, 24-h ambulatory electrocardiographic (ECG) monitoring was performed before and during the first and last weeks of treatment. Of note, the quit rates were low, so there was much concomitant smoking and patch use in each group. Frequency of angina declined both in nicotine and placebo groups, with no difference between treatments. Ambulatory ECG monitoring revealed no differences in arrhythmias or ST segment depression changes in nicotine- versus placebo-treated patients. Plasma nicotine concentrations averaged 14.1 ng/ml with transdermal nicotine in those who did and 21.1 ng/ml in those who did not quit smoking. Joseph et al. (103) recently reported the results of a large Veterans Affairs cooperative study of 584 smokers with cardiovascular disease. Patients received a 10-week course of transdermal nicotine (beginning at 21 mg/day and tapering to 7 mg/day) or placebo. Many participants continued to smoke cigarettes. The incidence of primary end points (death, myocardial infarction, cardiac arrest and admission to the hospital for increased severity of angina, arrhythmias or congestive heart failure) was similar in both groups (nicotine group: 5.4%; placebo group: 7.9%). These two studies (102,103) found no evidence of aggravation of coronary artery disease by NRT.

A recent experimental study (104) further supports the safety of transdermal nicotine, even in the setting of concomitant cigarette smoking, in patients with severe coronary artery disease. Thirty-six male smokers with a baseline ≥5% reversible perfusion defect by quantitative thallium-201 single-photon emission computed tomography were treated with 14- and 21-mg nicotine patches sequentially. Despite instructions to stop, most continued smoking, although they smoked fewer cigarettes per day. In the setting of increasing plasma nicotine levels (average: 15.8 ng/ml at baseline, 24.2 ng/ml for 14-mg nicotine patches, 30.4 ng/ml for 21-mg nicotine patches), there was a highly significant reduction in total exercise-induced perfusion defect size (average: 17.5% at baseline, 12.6% for 14-mg nicotine patches, 11.8% for 21-mg nicotine patches). No patient had a significant increase in myocardial ischemia while using nicotine patches. The progressive reduction in defect size was most closely related to the reduction in the blood carboxyhemoglobin concentration, which had decreased as a consequence of smoking fewer cigarettes. This study (104) suggests that carbon monoxide or some other component of tobacco smoke rather than nicotine is most important in limiting myocardial nutrient supply in patients with coronary heart disease. In that the perfusion defect size is known to have predictive implications for future myocardial infarction or death, or both (105), this study (104) suggests that treatment with transdermal nicotine is not hazardous in patients with coronary heart disease and may even reduce cardiovascular risk in continuing smokers if the smoking rate is reduced.

Risk Versus Benefit Considerations: Cigarette Smoking Versus NRT

In summary, cigarette smoking appears to precipitate acute cardiac events by at least three mechanisms. One mechanism, and perhaps the most important, is by producing a hypercoagulable state and promoting thrombosis. Studies with high doses of nicotine in animals suggest that this effect could be due to significantly increased levels of circulating epinephrine released by bolus dose nicotine. Importantly, such effects do not appear to be present during NRT with transdermal nicotine or nicotine gum. A second mechanism is the delivery of carbon monoxide, which limits oxygen delivery to the heart. This is a problem with cigarette smoking but not NRT. A third mechanism is through hemodynamic effects of nicotine. These include an increase in heart rate and blood pressure, which in turn increase myocardial work and oxygen demand, as well as constriction of coronary arteries, which would impair blood flow and oxygen supply to the heart.

The data presented in this review indicate that nicotine delivered by nicotine polacrilex gum or transdermal nicotine

has similar or lesser effects than cigarette smoking with respect to increasing myocardial work. No data are available on the effects of transdermal nicotine on coronary blood flow. However, because the vasoconstricting effects of nicotine appear to be mediated by sympathetic nervous system activation, and we have found that transdermal nicotine produces less sympathetic activation than does cigarette smoking, it is likely that transdermal nicotine would have no greater, and probably less, an effect than cigarette smoking on coronary vascular resistance.

The risk of smoking while using nicotine replacement products appears not to be greater than the risk of smoking alone. The explanation presumably lies in the flat dose–response relation for nicotine (106,107) and the fact that even when people smoke ad libitum during NRT, the total intake of nicotine is no more than modestly increased compared with that during usual smoking (108). Because smoking is usually substantially reduced during NRT compared with that before quitting, it is likely that the risk of cardiovascular events will be less, even with concurrent smoking, because it is smoking that carries with it the greatest burden of cardiovascular risk.

The risks of NRT in patients with cardiovascular disease have not been fully elucidated, but available data on patients with cardiovascular disease as well as experimental studies of the pharmacokinetics and pharmacodynamics of nicotine in healthy smokers, suggest that the risk is not great. In contrast, cigarette smoking remains the greatest cause of morbidity and mortality from cardiovascular disease in middle-aged people. NRT has been shown to substantially increase the likelihood of smoking cessation. The available information suggests that the benefit of NRT to aid smoking cessation in patients with coronary heart disease who cannot stop smoking without such therapy outweighs the risks of continued smoking or of NRT itself.

We thank Donna Causey, MD, Jane Gorsline, PhD, Charles Gorodetsky, MD, William Byrd, PharmD and Craig Pratt, MD for their comments and Kaye Welch for editorial assistance.

References

1. McBride PE. The health consequences of smoking: cardiovascular diseases. Med Clin North Am 1992;76:333–53.
2. Wilhelmsen L. Coronary heart disease: epidemiology of smoking and intervention studies of smoking. Am Heart J 1988;115:242–9.
3. Lepantalo M, Lassila R. Smoking and occlusive peripheral arterial disease. Eur J Surg 1991;157:83–7.
4. Nobuyoshi M, Masayuki A, Nosaka H, et al. Statistical analysis of clinical risk factors for coronary artery spasm: identification of the most important determinant. Am Heart J 1992;124:32–8.
5. Rivers JT, White HD, Cross DB, Williams BF, Norris RM. Reinfarction after thrombolytic therapy for acute myocardial infarction followed by conservative management: incidence and effect of smoking. J Am Coll Cardiol 1990;16:340–8.
6. Maouad J, Fernandez F, Hebert JL, Zamani K, Barrillon A, Gay J. Cigarette smoking during coronary angiography: diffuse or focal narrowing (spasm) of the coronary arteries in 13 patients with angina at rest and normal coronary angiograms. Cathet Cardiovasc Diagn 1986;12:366–75.
7. Galan KM, Deligonul U, Kern MJ, Chaitman BR, Vandormael MG. Increased frequency of restenosis in patients continuing to smoke cigarettes after percutaneous transluminal coronary angioplasty. Am J Cardiol 1988; 61:260–3.
8. Grines CL, Topol EJ, O'Neill WW, et al. Effect of cigarette smoking on outcome after thrombolytic therapy for myocardial infarction. Circulation 1995;91:298–303.
9. Green MS, Jucha E, Luz Y. Blood pressure in smokers and nonsmokers: epidemiologic findings. Am Heart J 1986;111:932–40.
10. Pickering T, Schwartz JE, James GD. Ambulatory blood pressure monitoring for evaluating the relationships between lifestyle, hypertension and cardiovascular risk. Clin Exp Pharmacol Physiol 1995;22:226–31.
11. Palatini P, Pessina AC, Graniero GR, et al. The relationship between overweight, life style and casual and 24-hour blood pressures in a population of male subjects with mild hypertension: the results of the HARVEST study. G Ital Cardiol 1995;25:977–89.
12. Cellina GU, Honour AJ, Littler WA. Direct arterial pressure, heart rate, and electrocardiogram during cigarette smoking in unrestricted patients. Am Heart J 1975;89:18–25.
13. Kool MJF, Hoeks APG, Struijker Boudier HAJ, Reneman RS, Van Bortel LMAB. Short- and long-term effects of smoking on arterial wall properties in habitual smokers. J Am Coll Cardiol 1993;22:1881–6.
14. Caro CG, Lever MJ, Parker KH, Fish PJ. Effect of cigarette smoking on the pattern of arterial blood flow: possible insight into mechanisms underlying the development of arteriosclerosis. Lancet 1987;2:11–3.
15. Pentecost B, Shillingford J. The acute effects of smoking on myocardial performance in patients with coronary arterial disease. Br Heart J 1964;26: 422–9.
16. Strauer BE, Mahmoud MA, Bayer F, Bohn I, Hahn B, Motz U. Global and regional wall motion and contractility of the left ventricle following cigarette smoking. Klin Wochenschr 1984;62 Suppl II:2–10.
17. Rietbrock N, Kunkel S, Wörner W, Eyer P. Oxygen-dissociation kinetics in the blood of smokers and nonsmokers: interaction between oxygen and carbon monoxide at the hemoglobin molecule. Naunyn Schmiedebergs Arch Pharmakol 1992;345:123–8.
18. Allred EN, Bleecker ER, Chaitman BR, et al. Short-term effects of carbon monoxide exposure on the exercise performance of subjects with coronary artery disease. N Engl J Med 1989;321:1426–32.
19. Aronow WS, Cassidy J, Vangrow JS, et al. Effect of cigarette smoking and breathing carbon monoxide on cardiovascular hemodynamics in anginal patients. Circulation 1974;50:340–7.
20. Calverley PMA, Leggett RJE, Flenley DC. Carbon monoxide and exercise tolerance in chronic bronchitis and emphysema. BMJ 1981;283:878–80.
21. Adams KF, Koch G, Chatterjee B, et al. Acute elevation of blood carboxyhemoglobin to 6% impairs exercise performance and aggravates symptoms in patients with ischemic heart disease. J Am Coll Cardiol 1988;12:900–99.
22. Sheps DS, Herbst MC, Hinderliter AL, et al. Production of arrhythmias by elevated carboxyhemoglobin in patients with coronary artery disease. Ann Intern Med 1990;113:343–51.
23. DeBias DA, Banerjee CM, Birkhead NC, Greene CH, Scott SD, Harrer WV. Effects of carbon monoxide inhalation on ventricular fibrillation. Arch Environ Health 1976;31:38–42.
24. Turino GM. Effect of carbon monoxide on the cardiorespiratory system. Carbon monoxide toxicity: physiology and biochemistry. Circulation 1981; 63:253A–9A.
25. Klein LW, Ambrose J, Pichard A, Holt J, Gorlin R, Teichholz LE. Acute coronary hemodynamic response to cigarette smoking in patients with coronary artery disease. J Am Coll Cardiol 1984;3:879–86.
26. Nicod P, Rehr R, Winniford MD, Campbell WB, Firth BG, Hillis LD. Acute systemic and coronary hemodynamic and serologic responses to cigarette smoking in long-term smokers with atherosclerotic coronary artery disease. J Am Coll Cardiol 1984;4:964–71.
27. Raymond R, Lynch J, Underwood D, Leatherman A, Mehdi R. Myocardial infarction and normal coronary arteriography: a 10-year clinical and risk analysis of 74 patients. J Am Coll Cardiol 1988;11:471–7.
28. Caralis DG, Ubeydullah D, Kern MJ, Cohen JD. Smoking is a risk factor for coronary spasm in young women. Circulation 1992;85:905–9.
29. Winniford MD, Jansen DE, Reynolds GA, Apprill P, Black WH, Hillis LD. Cigarette smoking-induced coronary vasoconstriction in atherosclerotic coronary artery disease and prevention by calcium antagonists and nitroglycerin. Am J Cardiol 1987;59:203–7.
30. Quillen JE, Rossen JD, Oskarsson HJ, Minor RL Jr, Lopez JAG, Winni-

ford MD. Acute effect of cigarette smoking on the coronary circulation: constriction of epicardial and resistance vessels. J Am Coll Cardiol 1993; 22:642–7.
31. Cryer PE, Haymond MW, Santiago JV, Shah SD. Norepinephrine and epinephrine release and adrenergic mediation of smoking-associated hemodynamic and metabolic events. N Engl J Med 1976;295:573–7.
32. Benowitz NL, Fitzgerald GA, Wilson M, Zhang Q. Nicotine effects on eicosanoid formation and hemostatic function: comparison of transdermal nicotine and cigarette smoking. J Am Coll Cardiol 1993;22:1159–67.
33. Winniford MD, Wheelan KR, Kremers MS, et al. Smoking-induced coronary vasoconstriction in patients with atherosclerotic coronary artery disease: evidence for adrenergically mediated alterations in coronary artery tone. Circulation 1986;73:662–7.
34. Peters RW, Benowitz NL, Valenti S, Modin G, Fisher ML. Electrophysiologic effects of cigarette smoking in patients with and without chronic beta-blocker therapy. Am J Cardiol 1987;60:1078–82.
35. Escobedo LG, Zack MM. Comparison of sudden and nonsudden coronary deaths in the United States. Circulation 1996;93:2033–6.
36. Craig WY, Palomaki GE, Haddow JE. Cigarette smoking and serum lipid and lipoprotein concentrations: an analysis of published data. BMJ 1989; 298:784–8.
37. Freeman DJ, Griffin BA, Murray E, et al. Smoking and plasma lipoproteins in man: effects on low density lipoprotein cholesterol levels and high density lipoprotein subfraction distribution. Eur J Clin Invest 1993;23:630–40.
38. Harats D, Ben-Naim M, Dabach Y, Hollander G, Stein O, Stein Y. Cigarette smoking renders LDL susceptible to peroxidative modification and enhanced metabolism by macrophages. Atherosclerosis 1989;79:245–52.
39. Stubbe I, Eskilsson J, Nilsson-Ehle P. High-density lipoprotein concentrations increase after stopping smoking. BMJ 1982;284:1511–3.
40. Pittilo RM, Woolf N. Cigarette smoking, endothelial cell injury and atherosclerosis. J Smoking-Related Dis 1993;4:17–25.
41. Asmussen I, Kjeldsen K. Intimal ultrastructure of human umbilical arteries: observations on arteries from newborn children of smoking and nonsmoking mothers. Circ Res 1975;36:579–89.
42. Celermajer DS, Sorensen KE, Georgakopoulos D, et al. Cigarette smoking is associated with dose-related and potentially reversible impairment of endothelium-dependent dilation in healthy young adults. Circulation 1993; 88:2149–55.
43. Nitenberg A, Antony I, Foult J-M. Acetylcholine-induced coronary vasoconstriction in young, heavy smokers with normal coronary arteriographic findings. Am J Med 1993;95:71–7.
44. Higman DJ, Greenhalgh RM, Powell JT. Smoking impairs endothelium-dependent relaxation of saphenous vein. Br J Surg 1993;80:1242–5.
45. Kiowski W, Linder L, Stoschitzky K, et al. Diminished vascular response to inhibition of endothelium-derived nitric oxide and enhanced vasoconstriction to exogenously administered endothelin-1 in clinically healthy smokers. Circulation 1994;90:27–34.
46. Beere PA, Glagov S, Zarins CK. Retarding effect of lowered heart rate on coronary atherosclerosis. Science 1984;226:180–2.
47. Duthie GG, Arthur JR, Beattie JAG, et al. Cigarette smoking, antioxidants, lipid peroxidation, and coronary heart disease. Ann N Y Acad Sci 1993; 686:120–9.
48. Morrow JD, Frei B, Longmire AW, et al. Increase in circulating products of lipid peroxidation (F_2-isoprostanes) in smokers. N Engl J Med 1995;332: 1198–203.
49. Heitzer T, Just H, Munzell T. Antioxidant vitamin C improves endothelial dysfunction in chronic smokers. Circulation 1996;94:6–9.
50. Petitti DB, Kipp H. The leukocyte count: associations with intensity of smoking and persistence of effect after quitting. Am J Epidemiol 1986;123: 89–95.
51. Bain BJ, Rothwell M, Feher MD, Robinson R, Brown J, Sever PS. Acute changes in haematological parameters on cessation of smoking. J Roy Soc Med 1992;85:80–2.
52. Grimm RH, Jr., Neaton JD, Ludwig W. Prognostic importance of the white blood cell count for coronary, cancer, and all-cause mortality. JAMA 1985;254:1932–7.
53. Hansen PR. Role of neutrophils in myocardial ischemia and reperfusion. Circulation 1995;91:1872–85.
54. FitzGerald GA, Oates JA, Nowak J. Cigarette smoking and hemostatic function. Am Heart J 1988;115:267–71.
55. Ernst E, Koenig W, Matrai A, Filipiak B, Stieber J. Blood rheology in healthy cigarette smokers. Arteriosclerosis 1988;8:385–8.
56. Fuster V, Badimon L, Badimon JJ, Chesebro JH. Mechanisms of disease: the pathogenesis of coronary artery disease and the acute coronary syndromes. N Engl J Med 1992;326:242–50.
57. Ernst E. Fibrinogen: its emerging role as a cardiovascular risk factor. Angiology 1994;45:87–93.
58. Smith JR, Landaw SA. Smokers' polycythemia. N Engl J Med 1978;298:6–10.
59. Benowitz NL. Pharmacologic aspects of cigarette smoking and nicotine addiction. N Engl J Med 1988;319:1318–30.
60. Okamura T, Noboru T. Mechanism underlying nicotine-induced relaxation in dog saphenous arteries. Eur J Pharmacol 1994;263:85–91.
61. Benowitz NL. Pharmacology of nicotine: addiction and therapeutics. Annu Rev Pharmacol Toxicol 1996;36:597–613.
62. Benowitz NL, Porchet H, Sheiner L, Jacob P III. Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum. Clin Pharmacol Ther 1988;44:23–8.
63. Benowitz NL, Jacob P, III, Jones RT, Rosenberg J. Interindividual variability in the metabolism and cardiovascular effects of nicotine in man. J Pharmacol Exp Ther 1982;221:368–72.
64. Sutherland G, Russell MAH, Stapleton J, Feyerabend C, Ferno O. Nasal nicotine spray: a rapid nicotine delivery system. Psychopharmacology 1992;108:512–8.
65. Bayer F, Bohn I, Strauer BE. Das kontraktionsverhalten des linken ventrikels unter nikotinexposition. Therapiewoche 1985;35:1968–74.
66. Waeber B, Schaller M, Nussberger J, Bussien J, Hofbauer KG, Brunner HR. Skin blood flow reduction induced by cigarette smoking: role of vasopressin. Am J Physiol 1984;249:H895–901.
67. Fewings JD, Rand MJ, Scroop GC, Whelan RF. The action of nicotine on the blood vessels of the hand and forearm in man. Br J Pharmacol 1966;26:567–79.
68. Diana JN, Qian S, Heesch CM, Barron KW, Chien CY. Nicotine-induced skeletal muscle vasodilation is mediated by release of epinephrine from nerve terminals. Am J Physiol 1990;259:H1718–29.
69. Woodman OL. Coronary vascular responses to nicotine in the anaesthetized dog. Naunyn Schmiedebergs Arch Pharmacol 1991;343:65–9.
70. Kaijser L, Berglund B. Effect of nicotine on coronary blood-flow in man. Clin Physiol 1985;5:541–52.
71. Przyklenk K. Nicotine exacerbates postischemic contractile dysfunction of stunned myocardium in the canine model: possible role of free radicals. Circulation 1994;89:1272–81.
72. Pfueller SL, Burns P, Mak K, Firkin BG. Effects of nicotine on platelet function. Haemostasis 1988;18:163–9.
73. Becker BF, Terres W, Kratzer M, Gerlach E. Blood platelet function after chronic treatment of rats and guinea pigs with nicotine. Klin Wochenschr 1988;66 Suppl XI:28–36.
74. Folts JD, Bonebrake FC. The effects of cigarette smoke and nicotine on platelet thrombus formation in stenosed dog coronary arteries: inhibition with phentolamine. Circulation 1982;65:465–9.
75. Mundal HH, Hjemdahl P, Gjesdal K. Acute effects of low dose nicotine gum on platelet function in nonsmoking hypertensive and normotensive men. Eur J Clin Pharmacol 1995;47:411–6.
76. Wennmalm A, Benthin G, Granström EF, Persson L, Peterson A, Winell S. Relation between tobacco use and urinary excretion of thromboxane A_2 and prostacyclin metabolites in young men. Circulation 1991;83:1698–704.
77. Wennmalm A. Nicotine stimulates prostaglandin formation in the rabbit heart. Br J Pharmacol 1977;59:95–100.
78. Wennmalm A, Alster P. Nicotine inhibits vascular prostacyclin but not platelet thromboxane formation. Gen Pharmacol 1983;14:189–91.
79. Nadler JL, Velasco JS, Horton R. Cigarette smoking inhibits prostacyclin formation. Lancet 1983;1:1248–50.
80. Nowak J, Murray JJ, Oates JA, FitzGerald GA. Biochemical evidence of a chronic abnormality in platelet and vascular function in healthy individuals who smoke cigarettes. Circulation 1987;76:6–14.
81. Barrow SE, Ward PS, Sleightholm MA, Ritter JM, Dollery CT. Cigarette smoking: profiles of thromboxane- and prostacyclin-derived products in human urine. Biochim Biophys Acta 1989;993:121–7.
82. Rångemark C, Benthin G, Granström EF, Persson L, Winell S, Wennmalm Å. Tobacco use and urinary excretion of thromboxane A_2 and prostacyclin metabolites in women stratified by age. Circulation 1992;86:1495–500.

83. Stefanovich V, Gore I, Kajiyama G, Iwanaga Y. The effect of nicotine on dietary atherogenesis in rabbits. Exp Mol Pathol 1969;11:71–81.
84. Strohschneider T, Oberhoff M, Hanke H, Hannekum A, Karsch KR. Effect of chronic nicotine delivery on the proliferation rate of endothelial and smooth muscle cells in experimentally induced vascular wall plaques. Clin Invest 1994;72:908–12.
85. Fisher ER, Rothstein R, Wholey MH, Nelson R. Influence of nicotine on experimental atherosclerosis and its determinants. Arch Pathol 1973;96: 298–304.
86. Csonka E, Somogyi A, Augustin J, Haberbosch W, Schettler G, Jellinek H. The effect of nicotine on cultured cells of vascular origin. Virchows Arch [A] 1985;407:441–7.
87. Thyberg J. Effects of nicotine on phenotypic modulation and initiation of DNA synthesis in cultured arterial smooth muscle cells. Virchows Arch B Cell Pathol 1986;52:25–32.
88. Booyse FM, Osikowicz G, Quarfoot AJ. Effects of chronic oral consumption of nicotine on the rabbit aortic endothelium. Am J Pathol 1981;102: 229–38.
89. Zimmerman M, McGeachie J. The effect of nicotine on aortic endothelium: a quantitative ultrastructural study. Atherosclerosis 1987;63:33–41.
90. Lin SJ, Hong CY, Chang MS, Chiang BN, Chien S. Long-term nicotine exposure increases aortic endothelial cell death and enhances transendothelial macromolecular transport in rats. Arterioscler Thromb 1992;12: 1305–12.
91. Krupski WC, Olive GC, Weber CA, Rapp JH. Comparative effects of hypertension and nicotine on injury-induced myointimal thickening. Surgery 1987;102:409–15.
92. Davis JW, Shelton L, Eigenberg DA, Hignite CE, Watanabe IS. Effects of tobacco and non-tobacco cigarette smoking on endothelium and platelets. Clin Pharmacol Ther 1985;37:529–33.
93. Hellerstein MK, Benowitz NL, Neese RA, et al. Effects of cigarette smoking and its cessation on lipid metabolism and energy expenditure in heavy smokers. J Clin Invest 1994;93:265–72.
94. Cluette-Brown J, Mulligan J, Doyle K, Hagan S, Osmolski T, Hojnacki J. Oral nicotine induces an atherogenic lipoprotein profile. Proc Soc Exp Biol Med 1986;182:409–13.
95. Quensel M, Agardh C-D, Nilsson-Ehle P. Nicotine does not affect plasma lipoprotein concentrations in healthy men. Scand J Clin Lab Invest 1989;49:149–53.
96. Thomas GAO, Davies SV, Rhodes J, Russell MAH, Feyerabend C, Säwe U. Is transdermal nicotine associated with cardiovascular risk? J R Coll Physicians Lond 1995;29:392–6.
97. Allen SS, Hatsukami D, Gorsline J, for the Transdermal Nicotine Study Group. Cholesterol changes in smoking cessation using the transdermal nicotine system. Prev Med 1994;23:190–6.
98. Hwang SL, Waldholt M. Heart attacks reported in patch users still smoking. Wall Street Journal 1992 14 July.
99. U.S. Food and Drug Administration. Transcript of the 23rd meeting of the U.S. Food and Drug Administration. 1992.
100. Anthonisen NR, Connett JE, Kiley JP, et al. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV_1. JAMA 1994;272:1497–505.
101. Murray RP, Bailey WC, Daniels K, et al. Safety of nicotine polacrilex gum used by 3,094 participants in the Lung Health Study. Chest 1996;109:438–45.
102. Working Group for the Study of Transdermal Nicotine in Patients with Coronary Artery Disease. Nicotine replacement therapy for patients with coronary artery disease. Arch Intern Med 1994;154:989–95.
103. Joseph AM, Norman SM, Ferry LH, et al. The safety of transdermal nicotine as an aid to smoking cessation in patients with cardiac disease. N Engl J Med 1996;335:1792–8.
104. Mahmarian JJ, Moye LA, Nasser GA, et al. A strategy of smoking cessation combined with nicotine patch therapy reduces the extent of exercise-induced myocardial ischemia. J Am Coll Cardiol. In press.
105. Marie PY, Danchin N, Durand JF, et al. Long-term prediction of major ischemic events by exercise thalium-201 single-photon emission computed tomography: incremental prognostic value compared with clinical, exercise testing, catheterization, and radionuclide angiographic data. J Am Coll Cardiol 1995;26:879–86.
106. Benowitz NL, Kuyt F, Jacob P III. Influence of nicotine on cardiovascular and hormonal effects of cigarette smoking. Clin Pharmacol Ther 1984;36: 74–81.
107. Benowitz NL, Jacob P III. Intravenous nicotine replacement suppresses nicotine intake from cigarette smoking. J Pharmacol Exp Ther 1990;254: 1000–5.
108. Foulds J, Stapleton J, Feyerabend C, Vesey C, Jarvis M, Russell MAH. Effect of transdermal nicotine patches on cigarette smoking: a double blind crossover study. Psychopharmacology 1992;106:421–7.
109. Rigotti NA, Eagle KA. Atrial fibrillation while chewing nicotine gum [letter]. JAMA 1986;255:1018.
110. Stewart PM, Catterall JR. Chronic nicotine ingestion and atrial fibrillation. Br Heart J 1985;54:222–3.
111. Ottervanger JP, Stricker BHC, Klomps HC. Transdermal nicotine: clarifications, side effects, and funding [letter]. JAMA 1993;269:1940.
112. Dacosta A, Guy JM, Tardy B, et al. Myocardial infarction and nicotine patch: a contributing or causative factor? Eur Heart J 1993;14:1709–11.
113. Warner JG, Jr., Little WC. Myocardial infarction in a patient who smoked while wearing a nicotine patch. Ann Intern Med 1994;120:695–6.
114. Jorenby DE, Smith SS, Fiore MC, et al. Varying nicotine patch dose and type of smoking cessation counseling. JAMA 1995;274:1347–52.
115. Pierce JR. Stroke following application of a nicotine patch [letter]. DICP 1994;28:402.
116. Jackson M. Cerebral arterial narrowing with nicotine patch. Lancet 1993; 342:236–7.
117. Henningfield JE, Stapleton JM, Benowitz NL, Grayson RF, London ED. Higher levels of nicotine in arterial than in venous blood after cigarette smoking. Drug Alcohol Depend 1993;33:23–9.
118. Hurt RD, Dale LC, Fredrickson PA, et al. Nicotine patch therapy for smoking cessation combined with physician advice and nurse follow-up. JAMA 1994;271:595–600.
119. Hurt RD, Dale LC, Offord KP, et al. Serum nicotine and cotinine levels during nicotine-patch therapy. Clin Pharmacol Ther 1993;54:98–106.
120. Sachs DP, Benowitz NL, Bostrum AG, Hansen MD. Percent serum replacement and success of nicotine patch therapy. Am J Resp Crit Care Med 1995;A688.
121. Kornitzer M, Boutsen M, Dramaix M, Thijs J, Gustavsson G. Combined use of nicotine patch and gum in smoking cessation: a placebo-controlled clinical trial. Prev Med 1995;24:41–7.
122. Schneider NG, Olmstead R, Mody FV, et al. Efficacy of a nicotine nasal spray in smoking cessation: a placebo-controlled, double-blind trial. Addiction 1995;90:1671–82.
123. Porchet HC, Benowitz NL, Sheiner LB, Copeland JR. Apparent tolerance to the acute effect of nicotine results in part from distribution kinetics. J Clin Invest 1987;80:1466–71.

Am J Public Health. 2010 December; 100(12): 2340–2342.
doi: 10.2105/AJPH.2010.199281
PMCID: PMC2978165

Novel Nicotine Delivery Systems and Public Health: The Rise of the "E-Cigarette"

Nathan K. Cobb, MD,✉ M. Justin Byron, MHS, David B. Abrams, PhD, and Peter G. Shields, MD

Nathan K. Cobb, M. Justin Byron, and David B. Abrams are with the Schroeder Institute for Tobacco Research and Policy Studies, Legacy Foundation, Washington, DC, and the Department of Health, Behavior, and Society, the Johns Hopkins Bloomberg School of Public Health, Baltimore, MD. Nathan K. Cobb and Peter G. Shields are with the Lombardi Comprehensive Cancer Center, Georgetown University School of Medicine, Washington, DC.
✉Corresponding author.
Correspondence should be sent to Nathan Cobb, MD, Research Investigator, Schroeder Institute for Tobacco Research and Policy Studies, 1724 Massachusetts Avenue NW, Washington, DC 20036 (e-mail: ncobb@legacyforhealth.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints/Eprints" link.

Contributors

All authors contributed substantially to the authorship of the editorial. N. K. Cobb is the guarantor and accepts full responsibility for the work.

Accepted July 26, 2010.

Inhalation of smoke from burning tobacco remains the most deadly risky behavior in the United States. For years, corporations have sought alternative methods to administer nicotine to the brain without the harms of combustion while retaining the immediate rewarding aspects of cigarettes that make them so profitable, pleasurable, and addictive. The latest attempt at reduced harm products is a heterogeneous collection of battery-driven inhalers termed by the World Health Organization (WHO) as electronic nicotine delivery systems (ENDS)[1] or more popularly as electronic cigarettes or e-cigarettes. These devices pose significant challenges to the public health community because their distribution and use has become widespread in the United States while simultaneously evading most regulatory structures. Ultimately, these devices force a close consideration of how the health and regulatory system evaluates claims of safety and harm reduction in a dynamic, consumer driven environment to ensure the broad protection of public health.

No standard definition of ENDS exists; different manufacturers use differing designs and incorporate a range of ingredients. Thus, a challenge to consumers, researchers, regulators, and policymakers is that specific attributes identified for any given ENDS brand may not apply to other brands. Three characteristics, however, appear common: (1) a cartridge containing a humectant carrier, such as propylene glycol, and often with nicotine in solution in different concentrations but no tobacco per se; (2) a tube into which the cartridge is inserted and through which the user inhales; and (3) a battery powered heating element across which the solution is drawn, causing the humectant to vaporize, forming a mist. Distributors also sell bottles of "juice" to refill cartridges with solutions that can contain high concentrations of nicotine and other substances.

Currently, the regulatory status of these devices remains in limbo in the United States. The Family Smoking and Tobacco Control Act of 2009 (HR 1256), provides for a new regulatory pathway for reduced harm products through the Food and Drug Administration (FDA) Center for Tobacco Products (CTP), but medicinal nicotine products remain regulated through the FDA Center for Drug Evaluation and Research (CDER). The CTP has a mandate to evaluate health claims provided by manufacturers, but inherent in the concept of harm reduction is a process of premarket evaluation and the demonstrable absence of unintended consequences on both health and behavior at individual and population levels.[2] Historically, tobacco companies have marketed oral and

other noncombustible tobacco products purporting to reduce harm without actually providing evidence of such. In March 2010, RJ Reynolds was found liable for falsely claiming harm reduction for the Eclipse cigarette—a predecessor of ENDS that delivered nicotine in a heated glycol solution drawn through a tobacco plug.[3]

Until recently, attempts to market nicotine products outside of medicinal nicotine replacement therapy (NRT) were subject to regulatory hurdles. Products were either regulated (i.e., FDA approved) cessation aids, such as the nicotine patch, or clearly tobacco industry–based and unregulated, such as Eclipse. Nonpharmaceutical products containing nicotine (such as lollipops and water) have been rapidly removed from the market with little controversy. In general, addiction liability and physiological harm are greatest with inhaled tobacco smoke, and least with medicinal NRT products.[2] In cigarettes and other tobacco products, the maximum dose of nicotine is limited by concentrations available in a fixed amount of tobacco. Although a cigarette may contain a highly toxic dose of 10–15mg of nicotine, serious poisoning is rare because presystemic metabolism and spontaneous vomiting limits the systemic absorption of nicotine in swallowed tobacco.[4] These upper limits may not apply to nicotine in high concentrations in ENDS or refill "juice" bottles if inhaled, swallowed, or spilled on the skin. Thus ENDS may introduce a new set of risks similar to those in nicotine-based pesticides and not normally present in leaf tobacco products.

WHAT REALLY MATTERS TO THE PUBLIC HEALTH COMMUNITY?

Go to

Cigarettes remain a major source of preventable mortality; an alternative to smoking that reduces exposure to toxins from tobacco combustion may be an acceptable strategy for harm reduction, provided it is evaluated on a premarket basis and introduces no new deleterious effects on either health or unintended changes in patterns of tobacco use behavior in the broader context of public health.[2,5] In adopting a harm-reduction language, manufacturers have promoted ENDS as an alternative to cigarettes rather than as a cessation aid, although ENDS are presumably used for cessation despite the absence of efficacy data. One manufacturer's lawyer stated: "we don't want people weaned off the e-cigarette, we want them smoking it as long as they smoked regular cigarettes."[6] Proponents have claimed that ENDS are logically safer than cigarettes since they avoid or reduce most of the carcinogens from tobacco, particularly its combustion.[5,7] Despite claims, the novel construction of ENDS has raised new challenging concerns of other potential risks, including appeal to and addiction of children (especially when flavors like strawberry or chocolate are added), displacement of effective cessation, long-term inhalation of propylene glycol, chemical contamination, uncontrolled levels of nicotine, misleading advertising of contents, variable nicotine delivery leading to unclear absorption mechanics or even potentially lethal systemic delivery, and accidental ingestion by young children because ENDS and "juice" are generally not sold in child resistant containers, are readily obtained via the Internet, and, for some refill kits, even come with a syringe.

WHAT DO WE CURRENTLY KNOW?

Go to

Based on FDA testing[8] and independent tseting of 2 ENDS brands by our group (full report available on request), we know that despite claims, nicotine varies across manufacturers, devices, cartridges, and, even, puff to puff. Such variations make generalizations of any testing results difficult; nonetheless we found the nicotine in the tested ENDS cartridges was 3- to 5-fold less than claimed (Table 1). Ultimately, the nicotine in the delivered vapor in the products tested is a fraction of that in the cartridge, and plasma testing suggests that current designs produce little systemic delivery of nicotine.[8–10] This may stem from any number of reasons; our testing of one device demonstrated an abrupt fall-off in delivery after the first 10 puffs, possibly from a rectifiable manufacturing defect, such as inconsistent current delivery. Triggering lag time from the pressure sensor or heating element may produce a nonlinear delivery curve per puff, causing shorter test puffs to have low nicotine delivery and deeper inhalations to have much more. The pH of the delivered solution may result in an ionized form of nicotine that is slowly absorbed through the tissue membranes, delaying uptake. At

minimum, the variability in tested ENDS indicates poor quality control, so their addiction liability remains unclear.

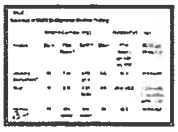


TABLE 1

Summary of ENDS (E-Cigarette) Nicotine Testing

Based on products tested, our results and the FDA's[8] confirm a manufacturer-sponsored study[11] demonstrating tobacco specific impurities and nitrosamines in cartridges at much lower levels than those found in cigarette smoke. Potentially concerning, and consistent with poor quality control, was the presence of humectants other than propylene glycol—in our case, glycerin, and for the FDA[8] diethylene glycol. The latter has a history of mass poisonings and deaths when inadvertently substituted for propylene glycol in consumer products.[12] The additional presence of irritants, solvents, genotoxins, and animal carcinogens (e.g., butyl acetate, diethyl carbonate, benzoic acid, quinoline, dioctyl phthalate 2,6-dimethyl phenol) is of unclear significance but needs further consideration.

RESEARCH, REGULATION, AND POLICY IMPLICATIONS

Go to

Although the tested ENDS delivered lower nicotine levels than advertised, without regulatory oversight there are no limits on increasing the dose or probability of accidental ingestion. Aftermarket selling of concentrated "juice" is worrisome—one supplier touts a solution containing 54mg of nicotine per mL (over 1.5 g per 30 mL bottle).[13] Propylene glycol is common in some oral and topical products but has not been studied rigorously for long-term inhalational safety in humans. Poor quality control raises additional concerns about other possibly lethal ingredients. Despite these concerns, the regulatory status of ENDS in the United States remains unclear. After asserting that ENDS are drug delivery systems, the FDA was met with a lawsuit.[14] The court ruling that ENDS are not drug delivery devices is under appeal, but the ruling is unclear about whether ENDS should be regulated by the FDA's traditional CEDR or the new CTP. Critically, despite the FDA action, ENDS remain widely available in the United States,[14] although through regulation they have been effectively banned in many other countries such as Australia, Canada, Singapore and Brazil owing to lack of safety or efficacy data.[5]

The ENDS tested so far have demonstrated poor quality control; toxic contaminants, albeit at low levels; misrepresentation of the nicotine delivered; and insufficient evidence of overall public health benefit. Ongoing, rigorous safety testing is needed, including determining real-world use patterns and further laboratory testing across device constructions to determine actual systemic nicotine delivery and exposure to harmful constituents. We recognize a manufacturer's desire to market their product and advocates who say ENDS are logically safer than cigarettes. However, to allow their unregulated sale on presumption is not protecting public health. ENDS should be removed from the market and permitted back only if and when it has been demonstrated that they are safe, that their benefits outweigh their harms to overall public health, and that a comprehensive regulatory structure has been established under an appropriate FDA division. It is possible that ENDS-like devices will eventually provide safer alternatives to smoking that do not increase uptake among youths, that foster cessation, and that are less harmful or addictive than cigarettes. Until then, health and safety claims based on assumptions are unacceptable.

Acknowledgments

Go to

The study was funded in part by a grant from the National Cancer Institute (5R01CA114377; Laboratory-Based Evaluation of Tobacco Harm Reduction) and the American Legacy Foundation.

References

Go to

1. World Health Organization Study Group on Tobacco Regulation Tobreg scientific recommendation: devices designed for the purpose of nicotine delivery to the respiratory system in which tobacco is not necessary for

From: Am J Public Health. 2010 December; 100(12): 2340–2342.
doi: 10.2105/AJPH.2010.199281

TABLE 1

Summary of ENDS (E-Cigarette) Nicotine Testing

	Nicotine/Cartridge[a] (mg)			Nicotine/Puff (μcg)		
Product	Claim	FDA Report[a]	GU/SI[a]	Claim	FDA Report, per 100 -mL Puff	GU/SI, per 35-mL Puff
Smoking Everywhere[b]	16	5.98	3.23 ±0.5	NA	31.5	Not tested
Njoy[c]	18	6.76	4.07 ±0.54	NA	26.8–43.2	1.0 for puffs 1–10< 0.3 for puffs 11–50
Nicotrol Inhaler[d]	10	Not tested	Not tested	50	15.2	Not tested

Note. ENDS = electronic nicotine delivery system; FDA = US Food and Drug Administration; GU = Georgetown University SI = Schroeder Institute.

[a]We tested 3 cartridges from each manufacturer under ISO (International Organization for Standards) smoking conditions; extracts were analyzed by gas chromatography by Arista Labs Inc. (Richmond, VA).
[b]Smoking Everywhere Inc, Sunrise, FL.
[c]Njoy Inc, Scottsdale, AZ.
[d]Pfizer Inc, New York, NY.

their operation. : Report on the Scientific Basis of Tobacco Product Regulation: Third Report of a WHO Study Group. Geneva: World Health Organization; 2009.

2. Zeller M, Hatsukami D., Strategic Dialogue on Tobacco Harm Reduction Group. The strategic dialogue on tobacco harm reduction: A vision and blueprint for action in the US. Tob Control. 2009;18(4):324–332. [PubMed]

3. State of Vermont v. RJ Reynolds Tobacco Co 2010: Available at: http://www.vermontjudiciary.org/TCDecisionCvl/2010-3-10-1.pdf. Accessed March 12, 2010.

4. Centers for Disease Control and Prevention (CDC) Ingestion of cigarettes and cigarette butts by children–Rhode Island. MMWR Morb Mortal Wkly Rep. 1997;46(6):125–128. [PubMed]

5. Henningfield JE, Zaatari GS. Electronic nicotine delivery systems: emerging science foundation for policy. Tob Control. 2010;19(2):89–90. [PubMed]

6. Lawyers ask judge to lift ban on electronic cigarettes. Available at: http://www.law.com/jsp/article.jsp?id=1202433141202&rss=newswire. Accessed November 25, 2009.

7. Seigel M. Electronic cigarettes jolt cynical opposition [Op-Ed]. Boston Herald. May 11, 2009.

8. US Food and Drug Administration Evaluation of e-cigarettes. 2009. Available at: http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf. Accessed March 6, 2010.

9. Eissenberg T. Electronic nicotine delivery devices: Ineffective nicotine delivery and craving suppression after acute administration. Tob Control. 2010;19(1):87–88. [PMC free article][PubMed]

10. Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M. Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. Tob Control. 2010;19(2):98–103. [PubMed]

11. Laugesen M. Safety Report on the Ruyan E-Cigarette Cartridge and Inhaled Aerosol. Christchurch, New Zealand: Health New Zealand Ltd; 2008.

12. Schep LJ, Slaughter RJ, Temple WA, Beasley DM. Diethylene glycol poisoning. Clin Toxicol (Phila). 2009;47(6):525–535. [PubMed]

13. Totally Wicked USA Totally wicked e-liquid. Available at: http://www.totallywicked-eliquid.com/products/totally-wicked-e-liquid/platinum-ice-54mg-mixed-juice-product.html. Accessed April 12, 2010.

14. Duff W. Judge orders FDA to stop blocking imports of e-cigarettes from china. New York Times. January 14, 2010.

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JULY 21, 2011

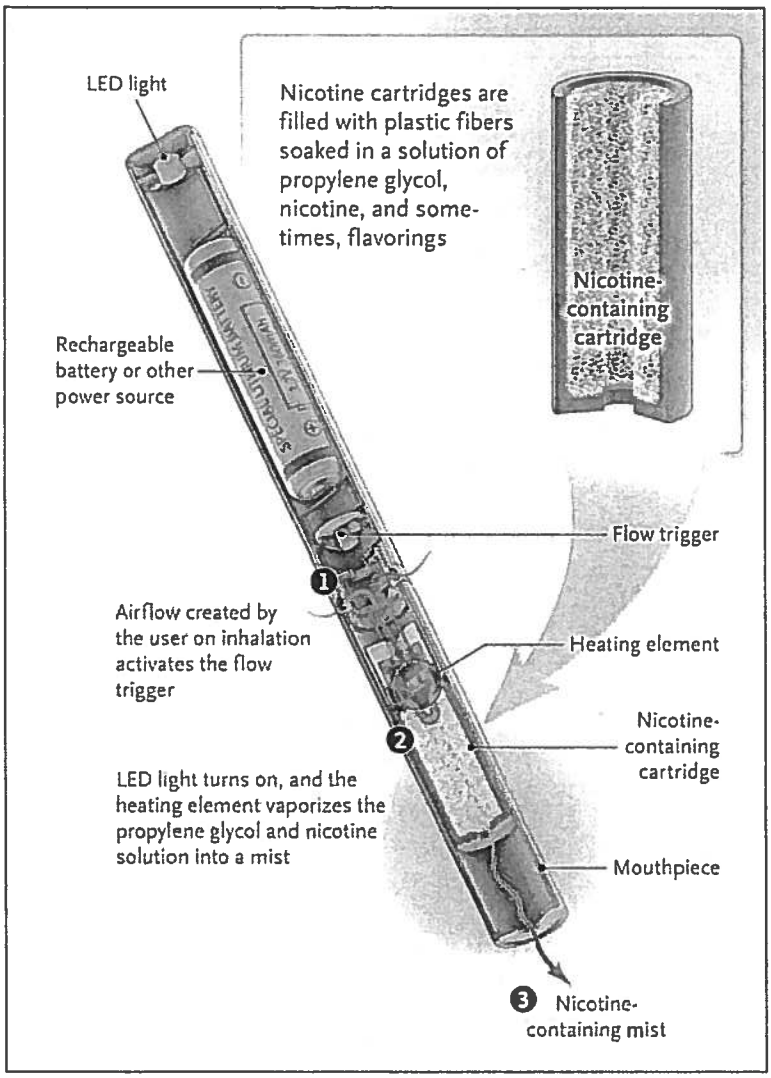
E-Cigarette or Drug-Delivery Device? Regulating Novel Nicotine Products

Nathan K. Cobb, M.D., and David B. Abrams, Ph.D.

On April 25, 2011, the Food and Drug Administration (FDA) announced its intention of regulating "electronic cigarettes" as tobacco products, having failed in its initial attempt to regulate them as drug-delivery devices. Previously, products delivering refined nicotine had either been regulated as pharmaceuticals (and subjected to the "safe and effective" standard used in drug approvals) or swiftly removed from the market to protect public safety. The FDA's decision came after the courts blocked the agency from regulating these products as drug-delivery devices, holding that under the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA), products containing nicotine derived from tobacco but making no therapeutic claims must be regulated as "tobacco products."[1] Together, this ruling and the FDA's announcement have upended the status quo. Unless and until the FDA asserts its authority under the FSPTCA, manufacturers can sell concentrated nicotine products directly to consumers, raising serious safety concerns.

Nicotine, an alkaloid found in tobacco, acts as an agonist of nicotinic acetylcholine receptors in the peripheral and central nervous systems. A stimulant and the addictive drug in tobacco products, nicotine drives those products' chronic use despite their well-known adverse health effects. Cigarettes typically contain 1 to 2 mg of nicotine, but nicotine has substantial toxic effects at higher doses. The estimated lethal dose for a child is 10 mg, the content of about half a pack of cigarettes. Smoking tobacco leads to nicotine deposition in the alveoli, absorption into the arterial circulation, and delivery to the brain within seconds. Such instant gratification makes cigarettes the most addictive drug of abuse, with tobacco eclipsing cocaine and heroin in terms of users' reported difficulty in abstaining.

The misleading term "e-cigarette" refers to an aerosolizing delivery device mated with a disposable cartridge. The cartridge contains nicotine in solution in a humectant, usually propylene glycol. The devices vary in construction, generally consisting of a battery, a heating element, a power source, and a pressure switch, all embedded in a tube with a mouth-



piece and a socket for cartridge insertion (see diagram). When the user draws on the mouthpiece, the negative pressure closes the switch, causing the heating element to warm both the cartridge and passing air. This warming causes the humectant to aerosolize, so that water vapor accumulates and forms a visible fog when exhaled. Nicotine, flavorings, and other additives or contaminants are carried with the aerosol into the oral cavity.

Despite being marketed as cigarettes, these devices have more in common with pipes, multi-dose inhalers, nebulizers, or other devices loaded with a drug, whether regulated (such as albuterol) or illicit (such as cocaine). Currently, three related products are being sold: delivery devices, cartridges, and refill solutions. Cartridges generally contain up to 20 mg of nicotine and are device-specific; starter cartridges are bundled with each device sold but are primarily sold separately by the device manufacturer or other suppliers. Refill kits, including as much as a gram of nicotine in a small bottle, allow consumers to fill used cartridges with replacement solution at higher doses than they originally contained. Propylene glycol is the most common humectant, and manufacturers claim that it's safe in consumer products. However, the safety of inhaling it, particularly over an extended period, has not been studied in humans.

Despite the FDA's statements, what is necessary or sufficient to constitute an e-cigarette — the delivery device, the cartridges, their contents, or a combination of the three — remains unclear. Historically, similar inhaler devices have used mechanical heat — the Eclipse cigarette, for example, heated tobacco soaked in glycerol — or have lacked a heat source, like the Favor inhaler of the late 1980s, which therefore released no visible aerosol. Favor reached the market briefly but was removed by the FDA. After the technology was sold to a pharmaceutical company, it eventually earned FDA approval as a safe and effective smoking-cessation aid (like the nicotine patch and gum) and was rereleased as the Nicotrol inhaler. But nothing limits the current generation of devices to delivering nicotine: instructions for filling cartridges with marijuana hash oil can be found on YouTube.

Exactly what variants of such nicotine-delivery devices will be allowed on the market, regulated or unregulated, and what doses of nicotine they will be permitted to deliver, is unclear. This uncertainty is worrisome, given that testing of cartridges has revealed poor quality control and marked inter- and intra-manufacturer variability in nicotine content, as well as large deviations from the

content claimed on the label.[2] Testing of the vapor from the devices has revealed similar variability, including marked "puff-to-puff" variation.[3] Finally, testing of users in laboratory settings revealed minimal blood nicotine concentrations.[4] Marketing claims aside, the devices tested did not efficiently deliver nicotine, much less deliver it into the arterial blood as tobacco smoke does. Smokers attempting to use e-cigarettes for smoking cessation will most likely find them ineffective; indeed, their use may instead perpetuate smokers' addiction. Since evidence of both safety and cessation benefit is lacking, there is cause for concern that the devices will become "bridge products" for use in places where smoking is prohibited or as starter products that are attractive to young people or former smokers.

The ineffective nicotine delivery of today's models cannot be seen as a permanent limitation. Increasing the cartridges' nicotine concentration may increase deposition — marketers of refills advertise their escalating concentrations, and some sell bottles of solution containing enough nicotine to kill an adult if ingested. Manipulating the fluid by altering its acid–base status can increase bioavailability, since absorption in the mouth and proximal airways depends on the pH. Various temperature and flow characteristics may alter the particle size and absorption of the vapor. Finally, the lack of distal pulmonary delivery may not be an unsolvable problem[5]; modifications leading to arterial delivery could dramatically increase the risk of addiction and abuse, as well as that of serious overdose. In fact, shortly after the FDA's announcement, both Philip Morris and British American Tobacco purchased nicotine-inhaler technologies that promise pulmonary delivery — strategic decisions that are unlikely to be coincidental and almost surely presage future consumer products.

Ultimately, Congress, the courts, and the FDA must find an effective regulatory approach for nicotine products that minimizes risk and maximizes the public welfare. Refined nicotine delivered by inhaler devices should be included in any such regulatory scheme, as should tobacco products promising "reduced or modified risk." To address the latter, the FSPTCA offers a new public health standard, requiring manufacturers and the FDA to focus on the goal of reducing the number of people who die or are harmed by tobacco, taking into consideration the risks and benefits to the entire population. For refined nicotine to ever be safely marketed under these standards, regulation must also include strict requirements — no different from those for other consumer drug products — for evidence of safety, consistent specifications, quality control, and functional dose limitations.

Regardless of how regulation of refined nicotine occurs, it must ensure that no existing or future products slip through the cracks. Some e-cigarette proponents have argued that strict regulation or withdrawal of the devices from the market would harm current users, forcing them to return to smoking tobacco. In reality, both smokers and e-cigarette users have many alternatives: multiple nicotine products, approved, regulated, and deemed to be safe and effective by the FDA, are already widely available (in addition to other effective cessation tools, such as varenicline, bupropion, telephone quit-lines, and Web-based services). Pending more aggressive regulation, clinicians should advise patients wishing to use nicotine to stick to the FDA-regulated forms, such as patches, gum, lozenges, nasal spray — or even, perhaps, the existing FDA-approved inhaler.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Schroeder Institute for Tobacco Research and Policy Studies, American Legacy Foundation (N.K.C., D.B.A.), and the Pulmonary and Critical Care Division and Lombardi Comprehensive Cancer Center, Georgetown University Medical Center (N.K.C.) — both in Washington, DC; and the Department of Health, Behavior, and Society, Johns Hopkins Bloomberg School of Public Health, Baltimore (N.K.C., D.B.A.).

1. Deyton LR, Woodcock J. Regulation of e-cigarettes and other tobacco products. Silver Spring, MD: Food and Drug Administration, April 25, 2011. (http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm.)
2. Cobb NK, Byron MJ, Abrams DB, Shields PG. Novel nicotine delivery systems and public health: the rise of the "e-cigarette." Am J Public Health 2010;100:2340-2.
3. Trtchounian A, Williams M, Talbot P. Conventional and electronic cigarettes (e-cigarettes) have different smoking characteristics. Nicotine Tob Res 2010;12:905-12.
4. Eissenberg T. Electronic nicotine delivery devices: ineffective nicotine delivery and craving suppression after acute administration. Tob Control 2010;19:87-8.
5. Rose JE, Turner JE, Murugesan T, Behm FM, Laugesen M. Pulmonary delivery of nicotine pyruvate: sensory and pharmacokinetic characteristics. Exp Clin Psychopharmacol 2010;18:385-94. [Erratum, Exp Clin Psychopharmacol 2011;19:iii.]

E-Cigarettes: A Rapidly Growing Internet Phenomenon

Cyrus K. Yamin, BS; Asaf Bitton, MD, MPH; and David W. Bates, MD, MSc

Electronic cigarettes (e-cigarettes) aerosolize nicotine and produce a vapor that emulates that of cigarettes but purportedly has fewer traditional toxins than secondhand smoke. Although e-cigarettes are widely sold online and by retailers, new research suggests that they may contain unexpected toxins and may provide unreliable nicotine delivery. Many countries have already banned or strictly regulated e-cigarettes. Currently in the United States, e-cigarettes are exempt from regulation as drug-delivery devices. Meanwhile, the presence of e-cigarettes on the Internet, including in Web searches, virtual user communities, and online stores where people sell e-cigarettes on commission, is increasing rapidly. Physicians should be aware of the popularity, questionable efficacy claims, and safety concerns of e-cigarettes so that they may counsel patients against use and advocate for research to inform an evidence-based regulatory approach.

Ann Intern Med. 2010;153:607-609. www.annals.org
For author affiliations, see end of text.

The electronic cigarette (e-cigarette) is part of an emerging class of electronic nicotine-delivery systems. RUYAN Group (now Dragonite International), Beijing, China, patented e-cigarettes in 2004, and e-cigarettes are now available in the United States through the Internet and at mall kiosks and other retailers. The device has 3 parts: a plastic tube, an electronic heating element, and a liquid nicotine cartridge (**Figure**). The user clicks a button that releases a puff of vaporized nicotine and illuminates a fiery orange or blue tip that simulates the lit end of a cigarette. Even without a combustion reaction, a plume typically emerges.

E-cigarette companies advertise that their products do not produce secondhand smoke and are ecologically friendly (2 leading companies are named Green Smoke [North Miami Beach, Florida] and Smoking Everywhere [Weston, Florida]). However, whether these claims are accurate is unclear. We intend to examine current research on e-cigarettes, analyze their growing presence online, and discuss regulatory issues, with a focus on helping physicians advise patients on these devices.

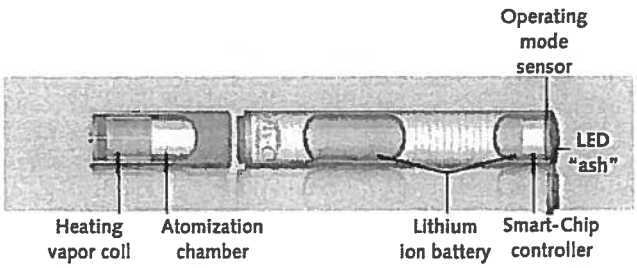
The quest for a safer cigarette is not new. R.J. Reynolds Tobacco (Winston–Salem, North Carolina) invented the Premiere cigarette in the 1980s and the Eclipse cigarette in the 1990s, both of which vaporized nicotine with low levels of combustion in an attempt to create a less noxious product (1). In 1998, Brown & Williamson Tobacco (Louisville, Kentucky) applied for a patent on a nicotine-vaporization method that aimed to minimize harm to nonsmoking bystanders.

Research on e-cigarettes to date is equivocal. In one of the first published studies, a laboratory analysis funded by RUYAN Group, investigators reported that e-cigarettes caused lower amounts of nicotine absorption than cigarettes and that their vapor contains no carbon monoxide, concluding that e-cigarettes represent "a safe alternative to smoking" (2). However, a 2009 U.S. Food and Drug Administration (FDA) laboratory analysis of e-cigarettes reported trace amounts of the harmful solvent diethylene glycol, the presence of nicotine in a "light" e-cigarette labeled as nicotine-free, and a 2-fold variation in nicotine release by each puff (3). An independent study in which aerosol density varied by puff in 8 e-cigarette brands further suggested nonuniform nicotine delivery (4). A 2010 study supported by RUYAN Group showed that e-cigarettes reduced the desire to smoke cigarettes but not nicotine withdrawal compared with placebo (5). However, a study by Vansickel and colleagues (6) found that e-cigarettes did not increase plasma nicotine concentrations and only modestly reduced the desire to smoke cigarettes. To date, prolonged smoking abstinence rates in e-cigarette users have not been evaluated. Despite the lack of smoking cessation data, a recent survey reported that the most frequently cited reason (65% of respondents) for using e-cigarettes was to quit smoking (7).

Interest in e-cigarettes seems to be increasing rapidly, fueled in part by the Internet. Google labels "electronic cigarettes" as a breakout term, defined as a phrase that has experienced a change in growth greater than 5000%, with a very large increase over the past 2 years (8). In 2009, the monthly average number of unique visitors at www.smokingeverywhere.com was 250 000, dwarfing the 32 336 unique visitors of www.quitsmoke.gov, the most popular Web site on smoking cessation (9).

With 78% of Americans using the Internet and 60% seeking health information online (10), consumers are probably using the Internet as their main source of e-cigarette information. One novel approach used by e-cigarette companies is their Internet-based marketing strategy. These companies use "affiliate marketing schemes" in which product users can become distributors and earn profits from recruiting customers. In less than 5 minutes, someone can become a salesperson on commission, armed with an advertisement library of posters and pamphlets (11), customized business cards, and a Web forum to share strategies to maximize online presence. Podcasts advise sellers on search engine optimization, a way to increase market reach by having one's Web page appear first in Google search results searches. This advice seems to be succeeding: 8 of the top 10 results in a Google search for "electronic cigarette" link to e-cigarette shops (12). However, determining the actual number of e-cigarette users is elusive because companies do not release these data.

Figure. Schematic of an electronic cigarette.



Reproduced with permission from *American Journal of Health-System Pharmacy.* 2009;66:1740-2.

When health analysis about a product is sparse and consumers are also sellers, the potential for public and individual health harm is magnified. Affiliate marketing schemes are regulated by the Federal Trade Commission, which in 2009 set rules on Internet marketing. Before becoming an affiliate, a person agrees to not sell e-cigarettes to persons younger than 18 years or market e-cigarettes as a smoking cessation product, although e-cigarettes are advertised as a "smoking sensation" product and can be purchased from Web sites that do not verify age (13).

Another controversy is whether e-cigarettes can and should be regulated as drug-delivery devices or tobacco products. The FDA has warned against e-cigarette use and argued that e-cigarettes be classified as drug-delivery devices similar to nicotine inhalers (14). However, a judge recently granted an injunction by e-cigarette manufacturers to reject the FDA's stance that e-cigarettes are drug-delivery devices, thus preventing the FDA from banning e-cigarette imports (15). Although the FDA's appeal may yet result in e-cigarettes' classification as drug-delivery devices, they may eventually be classified under the new FDA tobacco jurisdiction because of their derivation from and similarity to other novel tobacco products (16). Some states, including New Jersey and New York, have tried to ban sales or disallow public use of e-cigarettes in accordance with existing smoking bans. Other countries, including Canada, Australia, Brazil, and Panama, have taken a more aggressive stance, banning e-cigarettes outright because of safety concerns and their unapproved regulatory status (17).

We contend that the e-cigarette boom presents important public health concerns on at least 3 fronts. First, e-cigarettes may pose a risk as starter products for nonusers of tobacco. Although candy-flavored tobacco products and e-cigarettes were recently banned by the FDA in efforts to hinder marketing toward children, the posturing of e-cigarettes as "green" and "healthy" could deceptively lure adolescents (13). E-cigarettes also may represent a way for adolescents and adults to skirt smoke-free indoor air laws (18).

Second, potential e-cigarette toxicities exist that are not well quantified. A recent study documented more than 13 700 poisonings from tobacco ingestion among children younger than 6 years between 2006 and 2008 (19). Similarly, a child playing with an e-cigarette could be exposed to nicotine from the device or from nicotine refill bottles, which contain a concentrated liquid to fill e-cigarettes and can easily be ordered online (20). The nicotine dose that could be ingested or absorbed transdermally could induce fatal overdose in children. Finally, e-cigarettes may have other toxins, even in their exhaled secondhand vapor.

Third, little empirical research exists to determine whether e-cigarettes have potential as smoking cessation products. Aggressive affiliate marketing tactics are equally likely to dissuade smokers attempting to quit and could promote relapse to smoking. E-cigarettes may be less toxic than their paper analogues and may be developed as smoking cessation products, but evidence supporting these theories is currently lacking. We urgently need high-quality objective research to evaluate e-cigarette companies' claims about harm reduction and smoking cessation potential.

Health professionals need to monitor the biological, social, and addictive effects of e-cigarettes and be aware of their rapid dissemination online. National health surveys that track trends in tobacco use also should inquire about e-cigarette use. Although the safety and efficacy of e-cigarettes is uncertain, we believe that clearly counseling patients against e-cigarette use, as well as other tobacco use, is prudent. Meanwhile, e-cigarette salespersons have open access to the public.

From Harvard Medical School, Brigham and Women's Hospital, and Harvard School of Public Health, Boston, Massachusetts.

Acknowledgment: The authors thank Jack Henningfield, Adam Wright, and Ayal Bitton for feedback on earlier versions of this manuscript.

Potential Conflicts of Interest: None disclosed. Forms can be be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M10-1447.

Corresponding Author: David W. Bates, MD, MSc, Division of General Medicine, Brigham and Women's Hospital, 1620 Tremont Street, Boston, MA 02120-1613; e-mail, dbates@partners.org.

Current author addresses and author contributions are available at www.annals.org.

References

1. NOVA Online. Search for a safe cigarette. "Safer" cigarettes: a history. Updated October 2001. Accessed at www.pbs.org/wgbh/nova/cigarette/history2.htm on 17 September 2010.
2. Laugesen M. Safety report on the Ruyan® e-cigarette cartridge and inhaled aerosol. Health New Zealand Ltd. 30 October 2008. Accessed at www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf on 17 September 2010.
3. Westenberger BJ. Evaluation of e-cigarettes. U.S. Food and Drug Administration. 4 May 2009. Accessed at www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf on 17 September 2010.

4. Trtchounian A, Williams M, Talbot P. Conventional and electronic cigarettes (e-cigarettes) have different smoking characteristics. Nicotine Tob Res. 2010;12: 905-12. [PMID: 20644205]
5. Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M. Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. Tob Control. 2010;19:98-103. [PMID: 20378585]
6. Vansickel AR, Cobb CO, Weaver MF, Eissenberg TE. A clinical laboratory model for evaluating the acute effects of electronic "cigarettes": nicotine delivery profile and cardiovascular and subjective effects. Cancer Epidemiol Biomarkers Prev. 2010;19:1945-53. [PMID: 20647410]
7. Etter JF. Electronic cigarettes: a survey of users. BMC Public Health. 2010; 10:231. [PMID: 20441579]
8. Google. Web search interest: electronic cigarettes. Google Insights for Search. January 2007 to January 2010. Accessed at www.google.com/insights/search/#cat=123&q=electronic%20cigarettes&date=1%2F2007%2037m&cmpt=q on 17 September 2010.
9. Compete. Site comparison of smokingeverywhere.com vs. smokefree.gov: September 2009 to July 2010. Accessed at http://siteanalytics.compete.com/smokingeverywhere.com+smokefree.gov/ on 17 September 2010.
10. Fox S, Jones S. The social life of health information. Pew Internet and American Life Project. 11 June 2009. Accessed at www.pewinternet.org/Reports/2009/8-The-Social-Life-of-Health-Information.aspx?r=1 on 17 September 2010.
11. Green Smoke. Affiliate banners & ads. Accessed at http://greensmoke.com/earn/source/index.htm on 17 September 2010.
12. Google search: e-cigarettes. Accessed at www.google.com/#hl=en&source=hp&q=e-cigarettes&aq=f&aqi=g10&aql=&oq=&fp=22b4dcbb1403dc0f on 17 September 2010.
13. Green Smoke. Electronic cigarette & e-cigarette kits. Accessed at http://greensmoke.com/ on 17 September 2010.
14. U.S. Food and Drug Administration. FDA's media briefing on electronic cigarettes [transcript]. 22 July 2009. Accessed at www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM173405.pdf on 17 September 2010.
15. Smoking Everywhere, Inc. v. U.S. Food and Drug Administration, 09-771 (RJL), 2010 WL 129667, *1 (DDC 2010).
16. Family Smoking Prevention and Tobacco Control Act, HR 1256, 111th Cong, 1st Sess (2009).
17. World Health Organization. WHO Study Group on Tobacco Product Regulation: Report on the Scientific Basis of Tobacco Product Regulation. 2009. Accessed at http://whqlibdoc.who.int/publications/2009/9789241209557_eng.pdf on 17 September 2010.
18. Henningfield JE, Zaatari GS. Electronic nicotine delivery systems: emerging science foundation for policy [Editorial]. Tob Control. 2010;19:89-90. [PMID: 20378582]
19. Connolly GN, Richter P, Aleguas A Jr, Pechacek TF, Stanfill SB, Alpert HR. Unintentional child poisonings through ingestion of conventional and novel tobacco products. Pediatrics. 2010;125:896-9. [PMID: 20403932]
20. E-Cigarette Forum. E-liquid reviews. Accessed at www.e-cigarette-forum.com/forum/e-liquid-reviews/ on 17 September 2010.

READERS' COMMENTS

Readers wishing to comment on published articles should use the "Comments: Submit a comment" option at www.annals.org. While this service is free to *Annals* subscribers, readers without subscriptions who wish to comment on articles may purchase temporary access.

NO PACKET MATERIAL FOR THIS ITEM

IX. Concluding Business

A. Announcements

B. Adjournment