CAROLYN B. MALONEY
CHAIRWOMAN

ONE HUNDRED SIXTEENTH CONGRESS

JAMES COMER
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
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January 26, 2021

Mr. Adam Johnson
Chief Executive Officer
Safeguard Medical
5555 Harrisburg Industrial Park Drive
Harrisburg, NC 28075

Dear Mr. Johnson:

I am requesting documents and information regarding the federal government's contracts with Safeguard Medical's subsidiary Combat Medical Systems for the purchase of the SAVe II and SAVe II+ ventilators. Reports and independent studies have indicated that the ventilators purchased by the federal government may not be appropriate for their intended purpose of treating COVID-19 patients, which raises serious questions about whether their purchase for nearly $70 million constitutes waste, fraud, or abuse.[1]

During the initial surge of COVID-19 in the spring of 2020, the federal government engaged in a massive effort to procure ventilators. By April 2020, after signing contracts with 11 different manufacturers, the federal government had secured the purchase of 200,000 ventilators.[2] One of those contracts provided for the Department of Defense (DOD) to purchase SAVe II ventilators from Combat Medical Systems for $16.2 million.[3]

Soon after this contract was signed, officials at the Department of Health and Human Services (HHS) reportedly concluded that the SAVe II ventilator model was inadequate to treat COVID-19 patients. HHS asked for an improved ventilator, which would become the SAVe

[1] *The U.S. Paid a Texas Company Nearly $70 Million for Ventilators that Were Unfit for COVID-19 Patients. Why?*, Washington Post (Jan. 7, 2021) (online at www.washingtonpost.com/nation/2021/01/07/us-ventilator-wont-work-covid-patients/).

[2] Rich Branson, et al., *The US Strategic National Stockpile Ventilators in Coronavirus Disease 2019: A Comparison of Functionality and Analysis Regarding the Emergency Purchase of 200,000 Devices*, CHEST Journal (Sept. 20, 2020) (online at https://journal.chestnet.org/article/S0012-3692(20)34505-0/fulltext#secsectitle0075). By August 31, 2020, the federal government had reduced its purchase agreements to 130,000 ventilators. *Id.*

[3] USAspending, *Definitive Contract: PIID SPE2D120FZ004* (online at www.usaspending.gov/award/CONT_AWD_SPE2D120FZ004_9700_SPE2D014D0001_9700).

II+.[4] On June 26, 2020, HHS entered into a contract with Combat Medical Systems for $62.5 million for "SAVe II+ kit and delivery." The obligated funds for the $62.5 million contract have all been outlaid.[5]

I am concerned that SAVe II and SAVe II+ ventilators may not be effective in treating COVID-19 patients. If that is the case, their purchase could constitute the waste of government funds and an endangerment of patients' lives.

The Simplified Automated Ventilator, or "SAVe," was designed by AutoMedx in the late 2000s after receiving support from the Defense Advanced Research Projects Agency (DARPA). It was designed for military use in frontline combat situations, not for hospital or intensive care.[6] On September 6, 2007, the Food and Drug Administration approved the use of the SAVe ventilator "in field hospitals, transport and pre-hospital environments."[7]

A 2011 government-supported research study assessed the appropriateness of stockpiling the SAVe I and SAVe II ventilators for a respiratory pandemic and concluded that "further testing for a longer duration is warranted prior to decisions to procure such devices on a large scale."[8] DARPA has stated that the SAVe I and SAVe II "were not developed, nor intended, to treat critically ill patients, such as those we are seeing with covid-19."[9]

I share similar concerns about the SAVe II+, which was hastily designed between April and June 2020 after HHS found the SAVe II insufficient for COVID-19. Combat Medical Systems claims that "the SAVe II underwent performance modifications," including increased volume rate and air pressure, to create the SAVe II+.[10] However, reports indicate that the supposed improvements did not make the SAVe II+ a viable option for treating COVID-19 patients.

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[4] *The U.S. Paid a Texas Company Nearly $70 Million for Ventilators that Were Unfit for COVID-19 Patients. Why?*, Washington Post (Jan. 7, 2021) (online at www.washingtonpost.com/nation/2021/01/07/us-ventilator-wont-work-covid-patients/).

[5] USAspending, *Definitive Contract: PIID 75A50120C00136* (online at www.usaspending.gov/award/CONT_AWD_75A50120C00136_7505_-NONE-_-NONE-).

[6] *Top 4 New Breakthrough Medical Devices: Live @ DARPATech*, Popular Mechanics (Oct. 1, 2009) (online at www.popularmechanics.com/science/health/a5513/4220228/).

[7] Food and Drug Administration, 510(k) Determination Letter for Simplified Automated Ventilator -- SAVe, No. K071221 (dated Sept. 6, 2007) (online at www.accessdata.fda.gov/cdrh_docs/pdf7/K071221.pdf).

[8] Robert P. Dickson, David L. Hotchkin, et al., *A Porcine Model for Initial Surge Mechanical Ventialtor Assessment and Evaluation of Two Limited Function Ventilators*, Critical Care Medicine, Vol. 39, 527 (Mar. 2011) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3683595/).

[9] *The U.S. Paid a Texas Company Nearly $70 Million for Ventilators that Were Unfit for COVID-19 Patients. Why?*, Washington Post (Jan. 7, 2021) (online at www.washingtonpost.com/nation/2021/01/07/us-ventilator-wont-work-covid-patients/).

[10] Combat Medical Systems, *SAVe II+* (online at https://combatmedical.com/product/save-ii-plus/) (accessed Jan. 11, 2021).

DOD medical workers who attempted to use the SAVe II+ ventilator on COVID-19 patients found it to be ineffective and may "kill [patients] just as fast as no ventilator at all." Numerous physicians have stated that the SAVe II+ ventilator does not perform as well as other ventilators and is not appropriate for COVID-19 patients.[11] An independent review of ventilators that the federal government procured for COVID-19 found that the SAVe II+ was "[n]ot for use in critically ill patients"—a warning received for only one other ventilator.[12]

The manufacturer AutoMedx's Chief Medical Officer Geoffrey Ling acknowledged in a recent interview, "if I had to choose between a SAVe II ventilator and a full-featured one, I would take the full-featured one right now," though he claimed that the SAVe II is "better than nothing."[13]

AutoMedx appears to be the beneficiary of a potentially tainted procurement process. For example, AutoMedx has close connections to key government decisionmakers who may have been involved in the $60-plus million purchase. Adrian Urias, a co-founder and current shareholder of AutoMedx, reportedly advised the Trump administration on the procurement of ventilators.[14]

AutoMedx also appears to have benefited from a concerning coincidence that the government's initial specifications were nearly identical to the specifications for the SAVe II ventilator. On March 21, 2020, HHS published a notice calling for information about ventilator production potential from manufacturers, with an attachment laying out specifications on minimum performance requirements.[15] These specifications bear a striking resemblance to the specifications in a brochure for the SAVe II system that had been posted on AutoMedx's website.[16] Reportedly, AutoMedx CEO James Evans told a reporter that the specifications came

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[11] *The U.S. Paid a Texas Company Nearly $70 Million for Ventilators that Were Unfit for COVID-19 Patients. Why?*, Washington Post (Jan. 7, 2021) (online at www.washingtonpost.com/nation/2021/01/07/us-ventilator-wont-work-covid-patients/).

[12] Rich Branson, et al., *The US Strategic National Stockpile Ventilators in Coronavirus Disease 2019: A Comparison of Functionality and Analysis Regarding the Emergency Purchase of 200,000 Devices*, CHEST Journal (Sept. 20, 2020) (online at https://journal.chestnet.org/article/S0012-3692(20)34505-0/fulltext#secsectitle0075).

[13] *The U.S. Paid a Texas Company Nearly $70 Million for Ventilators that Were Unfit for COVID-19 Patients. Why?*, Washington Post (Jan. 7, 2021) (online at www.washingtonpost.com/nation/2021/01/07/us-ventilator-wont-work-covid-patients/).

[14] *The U.S. Paid a Texas Company Nearly $70 Million for Ventilators that Were Unfit for COVID-19 Patients. Why?*, Washington Post (Jan. 7, 2021) (online at www.washingtonpost.com/nation/2021/01/07/us-ventilator-wont-work-covid-patients/).

[15] Department of Health and Human Services, *Request for Information (RFI) – Ventilators COVID-19*, Notice ID HHS-2020-RFI-COVID-19-1 (updated Mar. 23, 2020) (online at https://beta.sam.gov/opp/6e018f13932c4eb1b137dd604a259be9/view).

[16] AutoMedx, *Simplified Automated Ventilator II* (archived Jan. 7, 2017) (online at https://web.archive.org/web/20170107225046/http://automedx.biz/wp-content/themes/gravida/SAVeII.pdf).

from a *Respiratory Care* article, but the author of that article refuted that claim.[17] Below are the specifications side by side:

HHS COVID-19 Specifications

Minimum Ventilator Requirements

Control	Operating Modes:	Assist Control / Intermittent Mandatory Ventilation CPR Mode
	Primary Control:	Volume
	Secondary Control:	Pressure
	Breath Target:	Time
Rate	Flow Rate (LPM):	Up to 27
	Breath Rate (BPM):	8 - 20
Pressure (cmH2O)	Peak Inspiratory Pressure (PIP) Limit	10 - 70
	Peak End Expiratory Pressure (PEEP	0 - 10 --> 20 cmH2O
	Inspiratory Trigger Pressure	2
	Inadvertent PEEP	< 2
Volume (mL)	Tidal Volume	200 - 800
	Minute Volume	Max Min Vol 8 LPM --> 15LPM
Time (Seconds)	Inspiratory	0.75 - 2.00
	Expiratory	2.25 - 5.00
	I:E Ratio	Fixed at 1:2
Supplemental Oxygen	Input Flow Rate:	0 - 10 LPM
	FIO2:	21-100%
Operating Time	TV=500, RR=10, PEEP=0	Up to 12 hours
	TV=600, RR=10, PEEP=0	Up to 10 hours

SAVe II Brochure

Specifications

Control	Operating Modes:	Dual Control – Intermittent Mandatory Ventilation CPR Mode
	Primary Control:	Time
	Secondary Control:	Pressure
	Breath Target:	Volume
Rate	Flow Rate (LPM):	Up to 27
	Breath Rate (BPM):	8 – 30
Pressure (cmH2O)	Peak Inspiratory Pressure (PIP) Limit	10 - 60
	Peak End Expiratory Pressure (PEEP)	0 - 10
	Inspiratory Trigger Pressure	2
	Inadvertent PEEP	< 2
Volume (mL)	Tidal Volume	200 – 800
	Minute Volume	1600 – 8000
Time (Seconds)	Inspiratory	0.75 – 2.00
	Expiratory	2.25 – 5.00
	I:E Ratio	Fixed at 1:2
Supplemental Oxygen	Input Flow Rate:	0 – 10 LPM
	FIO_2:	21-100%
Operating Time	TV=500, RR=10, PEEP=0	Up to 10 hours

To assist in my investigation of this matter, please produce the following documents and information by February 9, 2021:

1. All documents and communications referring or relating to the $16.2 million and $62.5 million government contracts awarded to Combat Medical Systems for ventilators, including but not limited to documents and communications related to:

   a. Combat Medical Systems' interest in providing ventilators to or contracting with the federal government;
   b. any solicitation or request for proposals or offers;
   c. any offer, bid, or proposal from Combat Medical Systems, including type of competition and pricing information;
   d. Combat Medical Systems' contracts with the federal government;
   e. any agreements between Combat Medical Services and any subcontractors, vendors, or other third-party service providers on the $16.2 million and $62.5 million ventilator contracts; and
   f. all awards, modifications, and terminations of any contract;

2. A description of all negotiations with the federal government regarding ventilators for COVID-19, since January 1, 2020, identifying the agencies, offices and

[17] Rich Branson, et al., *The US Strategic National Stockpile Ventilators in Coronavirus Disease 2019: A Comparison of Functionality and Analysis Regarding the Emergency Purchase of 200,000 Devices*, CHEST Journal (Sept. 20, 2020) (online at https://journal.chestnet.org/article/S0012-3692(20)34505-0/fulltext#secsectitle0075).

government personnel involved, the time and manner of communication, and the topics discussed, including specific discussions regarding:

a. the specifications and performance of ventilators;
b. the intended use of ventilators;
c. the number and type of ventilators discussed; and
d. the price range of the ventilators;

3. All communications referring or relating to the federal government's purchase of ventilators involving, referring to, or relating to the following individuals:

a. Adrian Urias;
b. Adm. Brett Giroir;
c. Sec. Alex Azar;
d. Robert Kadlec;
e. Peter Navarro;
f. Jared Kushner;
g. Adam Boehler; and
h. Christopher Abbott;

4. A list of all Safeguard Medical or Combat Medical Systems employees or agents who communicated with the federal government regarding the subjects described in Requests 1, 2 and 3, including a description of the date, subject matter, and participants of any meetings or telephone conferences;

5. All contracts with the federal government for the purchase of SAVe, SAVe II, or SAVe II+ ventilators, including all amendments thereto, since January 1, 2015;

6. A list of all SAVe II and SAVe II+ ventilator sales, including model, quantity, price, purchaser, contract date, and delivery date, from January 1, 2019, to the present;

7. All contracts between AutoMedx and Combat Medical Systems regarding SAVe II or SAVe II+ ventilators, since January 1, 2015;

8. All studies, in-house, government-supported, and independent, regarding performance of SAVe, SAVe II, or SAVe II+ ventilators, including performance for the purposes of a respiratory pandemic or COVID-19 specifically;

9. A narrative description of the differences between the SAVe, SAVe II, and SAVe II+ ventilators, all documents sufficient to demonstrate those differences, and the marginal cost of producing the SAVe, SAVe II, and SAVe II+ ventilators; and

10. All documents regarding complaints from medical professionals or government officials that the SAVe II or SAVe II+ ventilator is inappropriate for use on COVID-19 patients.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Sincerely,

Raja Krishnamoorthi
Member
Committee on Oversight and Reform

Enclosure

cc: The Honorable Michael Cloud, Member

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.