

2016

STATE OF LIFE SCIENCES

HEALTHCARE
COMPLIANCE

SURVEY



Introduction

Healthcare compliance plays a crucial role in the success of a life sciences business. Consequently, we all have a keen interest in better understanding the healthcare compliance environment and gaining insights into how companies handle compliance challenges. To that end, Porzio Life Sciences has created the Life Sciences Healthcare Compliance Survey.

The following pages detail the responses gathered in 2016 from compliance professionals working in life sciences companies of all sizes, in a wide variety of industry sectors. We hope this information will serve as a useful benchmarking tool for you and your compliance program.

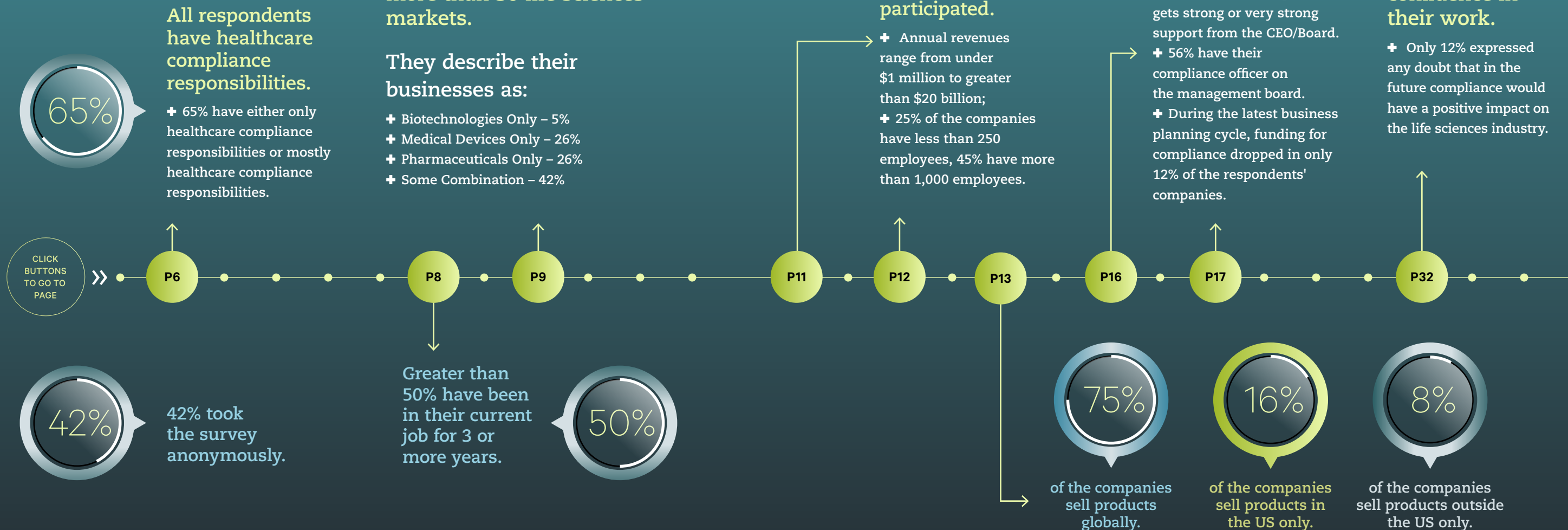
Porzio Life Sciences

Highlights

VALID RESPONDENTS IN THIS RESEARCH: **119**

Respondents were considered not valid if they:

- + Had no healthcare compliance responsibilities.
- + Answered only a few opening profile questions.



Among the limitations of this study:

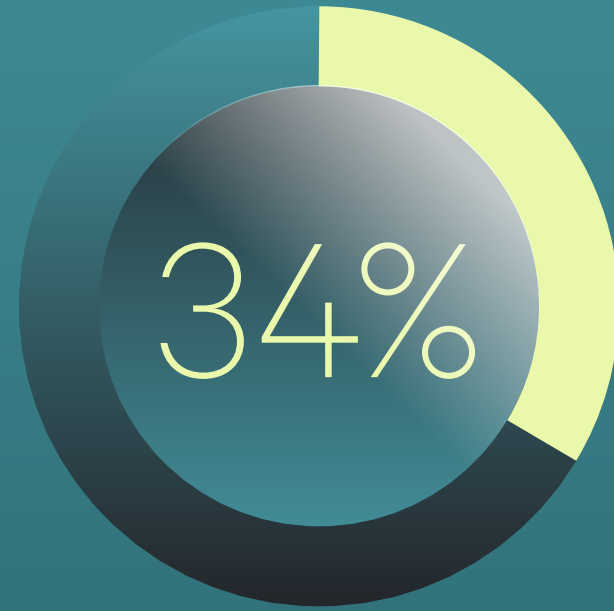
- + The answers are self-reported and cannot be objectively verified.
- + It is possible, though not confirmed, that more than one person from the same company are included in the data; if that did occur, they may have not offered the same answers regarding their company's healthcare compliance system/performance.
- + This is merely a snapshot from late 2016. Things could have changed since then.

More details and additional insights can be found on the ensuing pages.

Q1

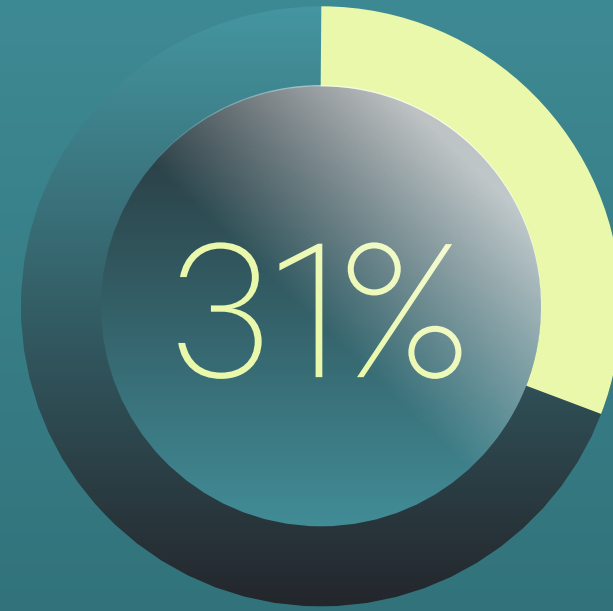
Complete the following sentence with the statement that best describes your current job:

My current job involves: _____.



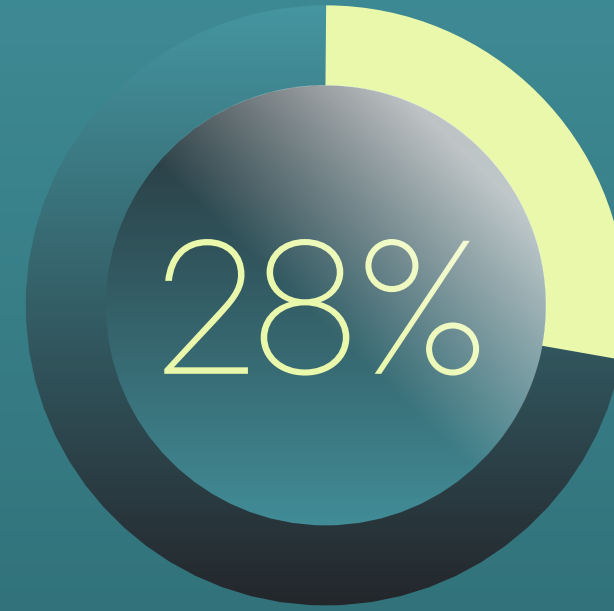
A

ONLY HEALTHCARE COMPLIANCE RESPONSIBILITIES



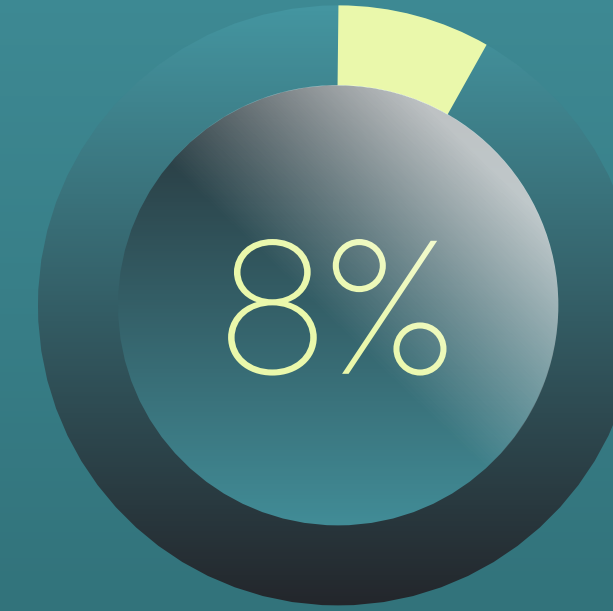
B

MOSTLY HEALTHCARE COMPLIANCE RESPONSIBILITIES; FEW OTHER COMPANY RESPONSIBILITIES



C

SOME HEALTH-CARE COMPLIANCE RESPONSIBILITIES AND SOME OTHER COMPANY RESPONSIBILITIES



D

FEW HEALTHCARE COMPLIANCE RESPONSIBILITIES; MOSTLY OTHER COMPANY RESPONSIBILITIES

ANSWERS

(Absolute #s)

A	Only healthcare compliance responsibilities	40
B	Mostly healthcare compliance responsibilities; few other company responsibilities	37
C	Some healthcare compliance responsibilities and some other company responsibilities	33
D	Few healthcare compliance responsibilities; mostly other company responsibilities	9

N=119

Q2

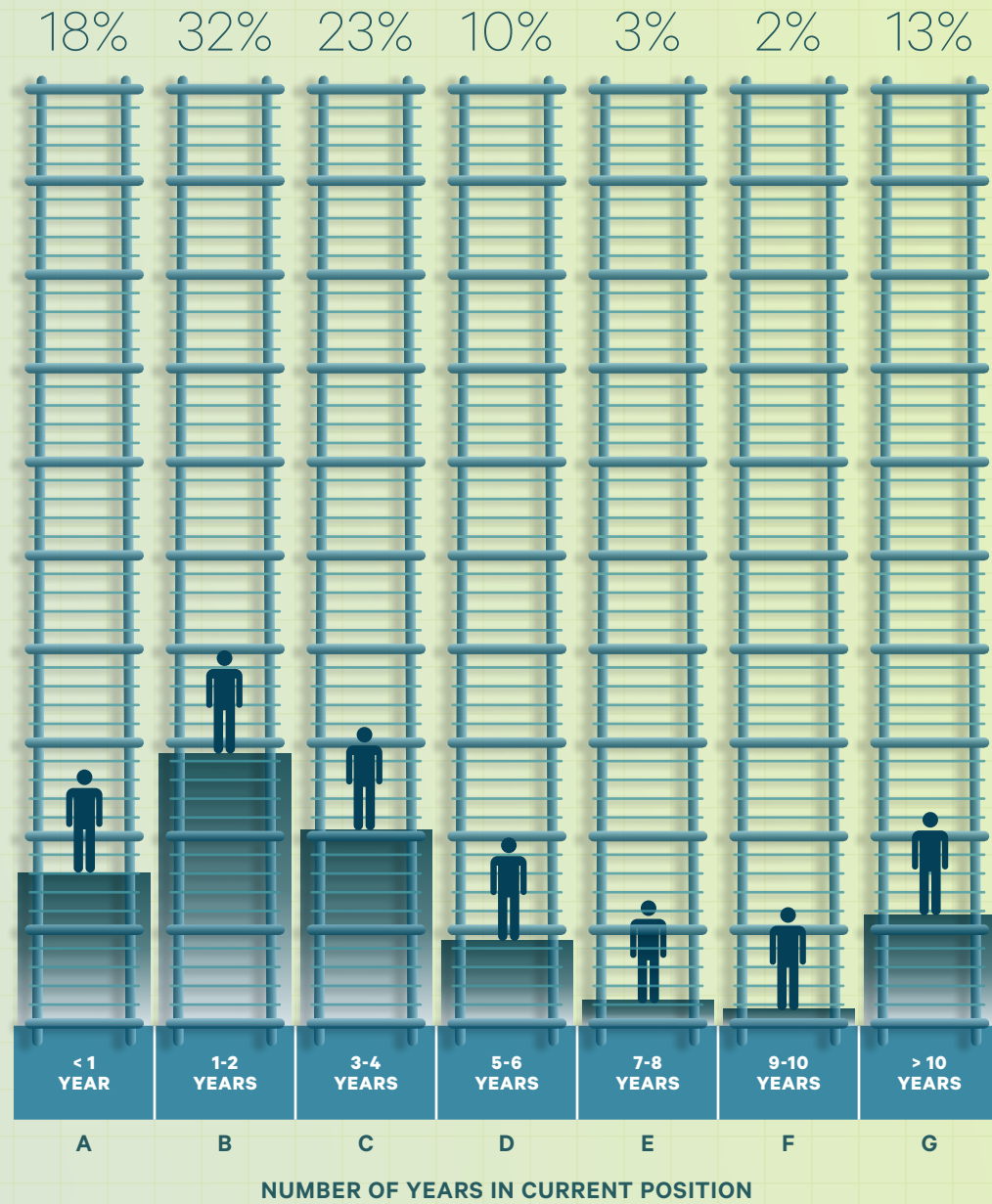
How many years have you been in your current position?

ANSWERS

(Absolute #s)

A	< 1 Year	21
B	1-2 Years	38
C	3-4 Years	27
D	5-6 Years	12
E	7-8 Years	4
F	9-10 Years	2
G	> 10 Years	15

N=119



Q3

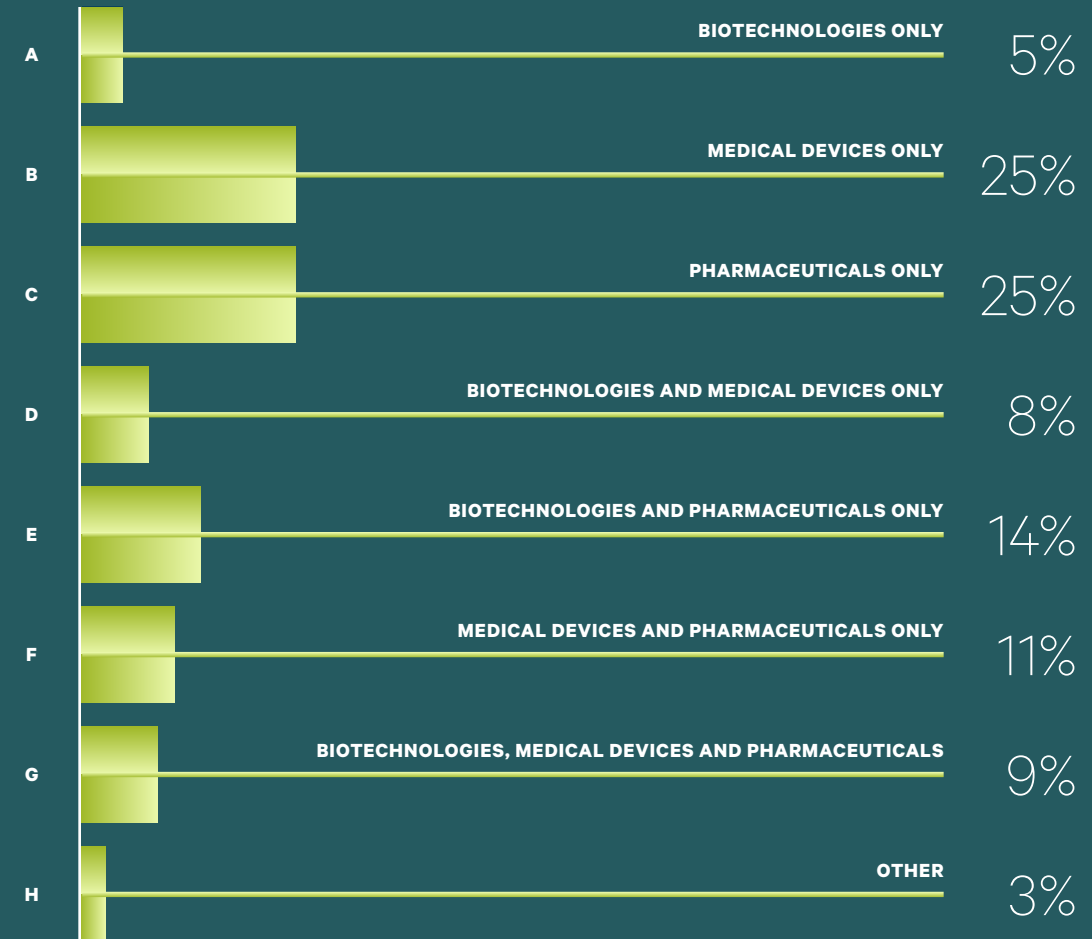
Indicate which of the following categories best describes the products your company sells.

ANSWERS

(Absolute #s)

A	Biotechnologies only	6
B	Medical devices only	30
C	Pharmaceuticals only	30
D	Biotechnologies and medical devices only	9
E	Biotechnologies and pharmaceuticals only	16
F	Medical devices and pharmaceuticals only	13
G	Biotechnologies, medical devices and pharmaceuticals	11
H	Other	3

N=118



Q4

The name of the industry(s)/market(s) - e.g. cardiovascular, gastrointestinal, neuromuscular, OB/GYN, orthopedics, oncology, orphan drugs - in which your company primarily operates is: _____.

ANSWERS (Absolute #s) N=115



Q5

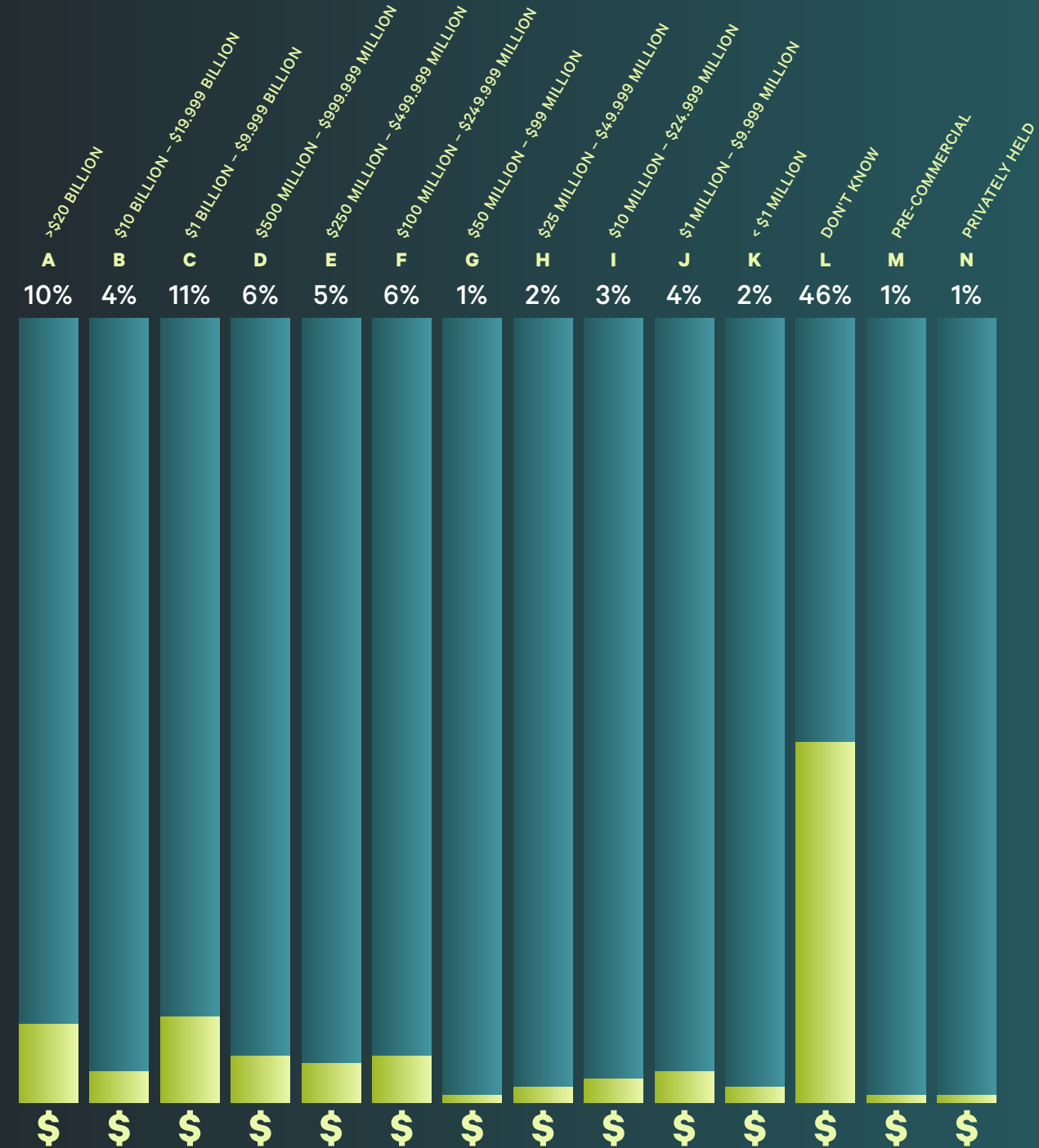
What is your company's annual revenue?

ANSWERS

(Absolute #s)

Revenue Category	Count
A > \$20 Billion	11
B \$10B - \$19.999B	4
C \$1B - \$9.999B	12
D \$500M - \$999.999M	7
E \$250M - \$499.999M	5
F \$100M - \$249.999M	6
G \$50M - \$99M	1
H \$25M - \$49.999M	2
I \$10M - \$24.999M	3
J \$1M - \$9.999M	4
K < \$1 Million	2
L Don't Know	50
M Pre-commercial	1
N Privately Held	1

N=109



Q6

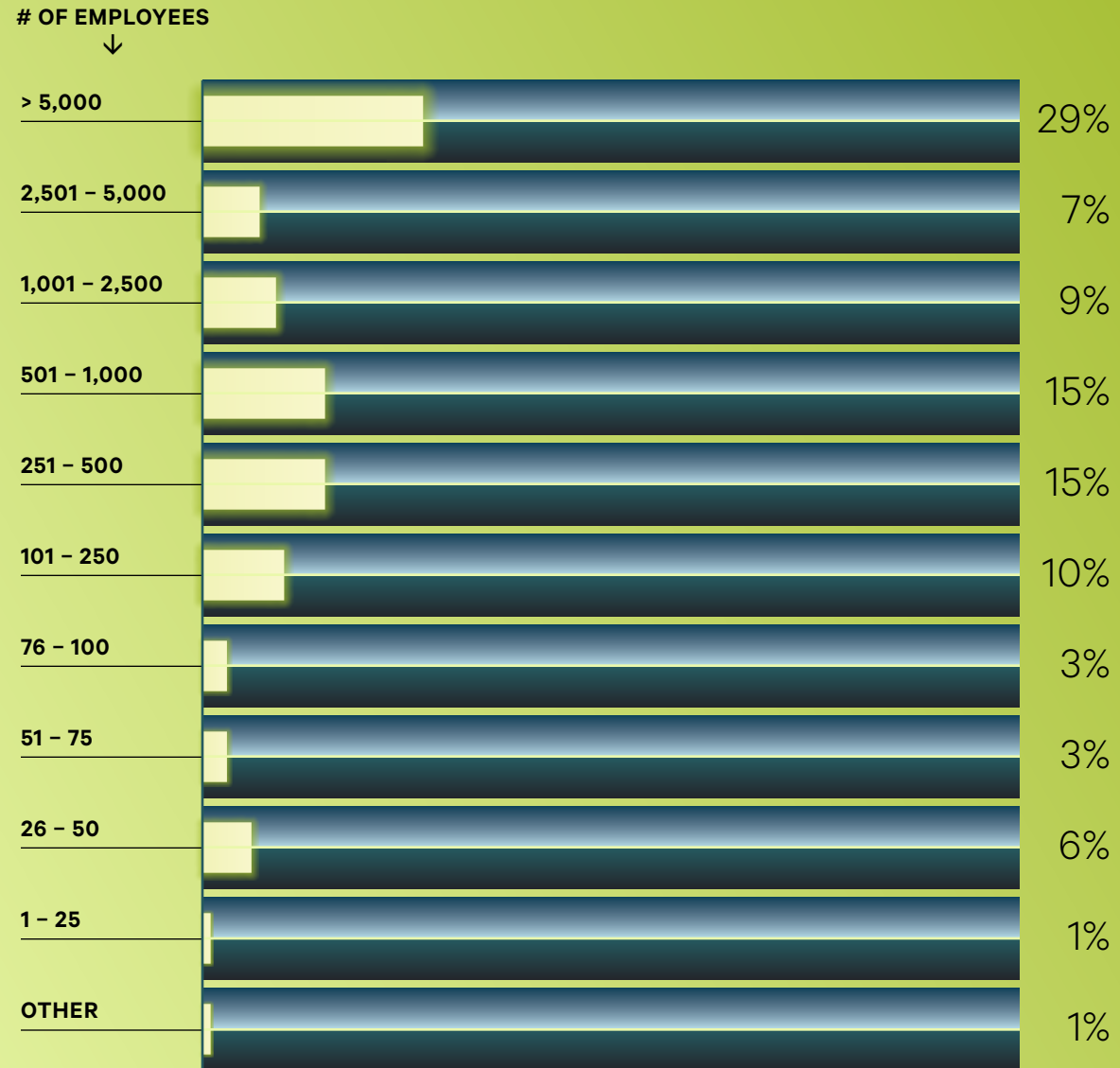
How many employees work at your company?

ANSWERS

(Absolute #s)

A	> 5,000	34
B	2,501 - 5,000	8
C	1,001 - 2,500	11
D	501 - 1,000	18
E	251 - 500	18
F	101 - 250	12
G	76 - 100	4
H	51 - 75	4
I	26 - 50	7
J	1 - 25	1
K	Other	1

N=118



Q7

Choose a phrase to complete the following sentence.

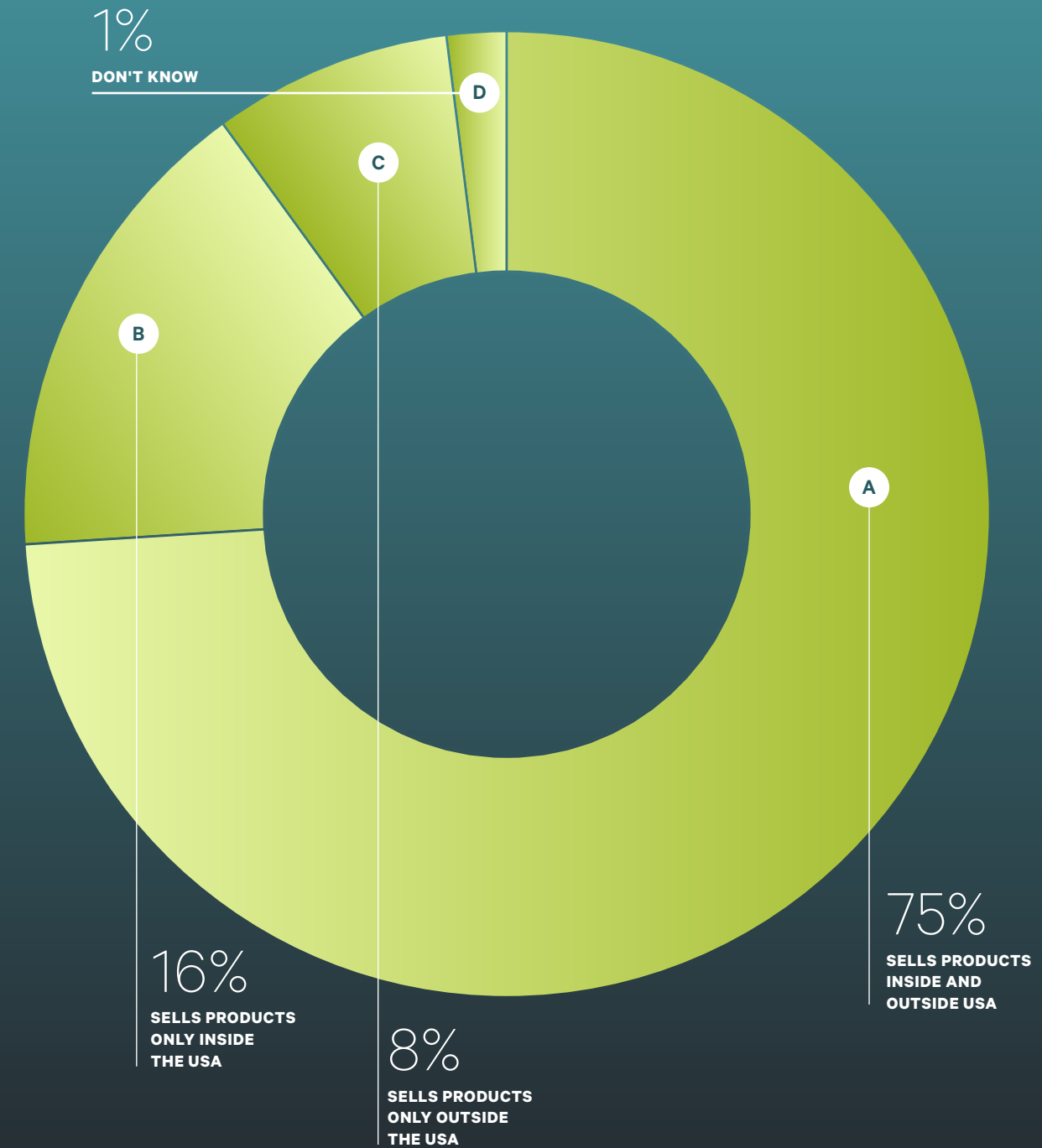
Our company sells products: _____ .

ANSWERS

(Absolute #s)

A	Inside and outside the United States	89
B	Only inside the United States	19
C	Only outside the United States	10
D	Don't know	1

N=119



Q8

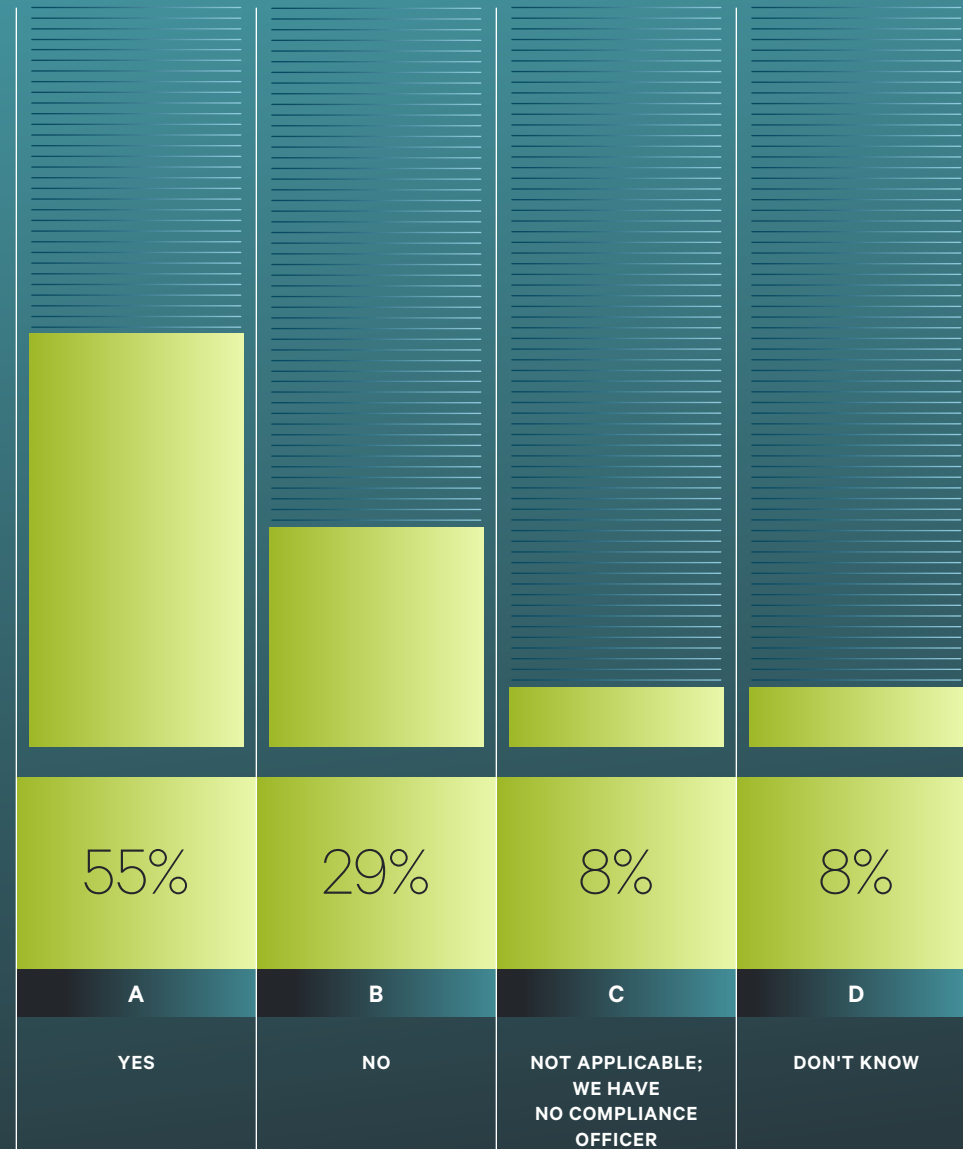
Is your Compliance Officer a member of the company's management board?

ANSWERS

(Absolute #s)

A	Yes	66
B	No	35
C	Not applicable; we have no compliance officer	9
D	Don't know	9

N=119



Q9

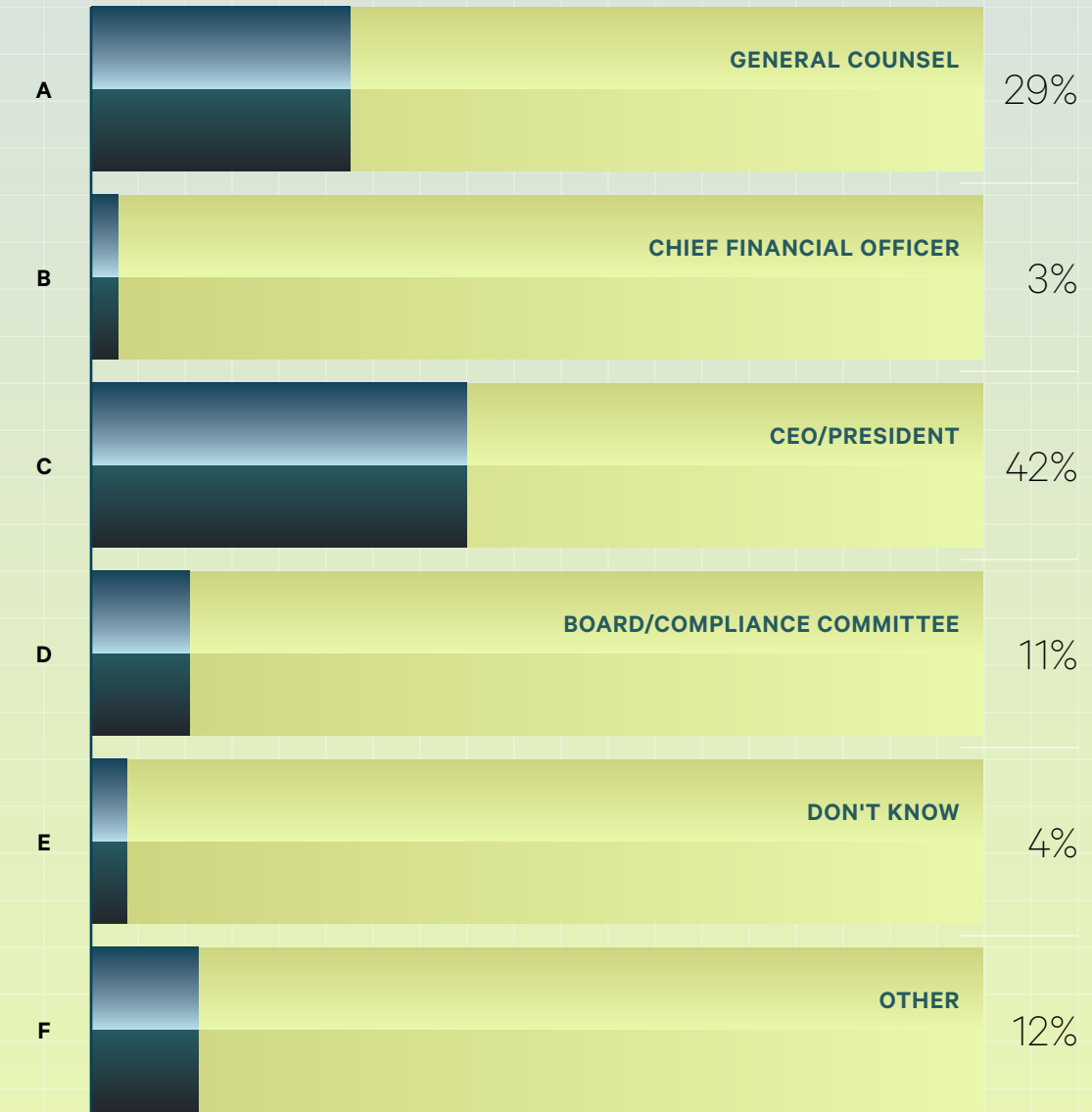
To whom does your company's Compliance Officer report?

ANSWERS

(Absolute #s)

A	General Counsel	29
B	Chief Financial Officer	3
C	CEO/President	42
D	Board/Compliance Committee	11
E	Don't Know	4
F	Other	12

N=101



Q10

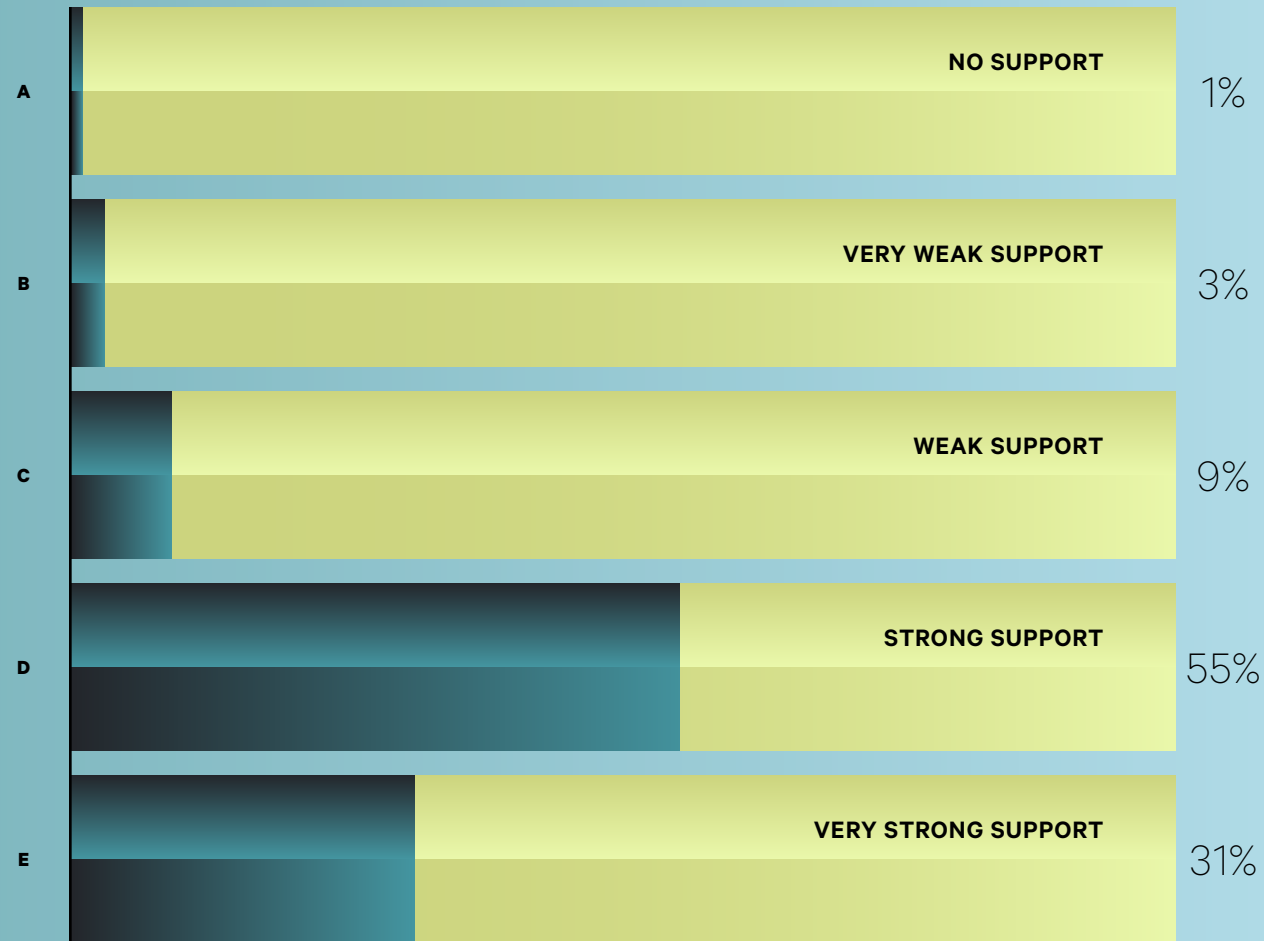
Choose the statement that best describes the support your company's healthcare compliance effort receives from your company's CEO/Board.

ANSWERS

(Absolute #s)

A	No support	1
B	Very weak support	3
C	Weak support	11
D	Strong support	65
E	Very strong support	37

N=117



Q11

Which phrase best completes the sentence to reflect your view?

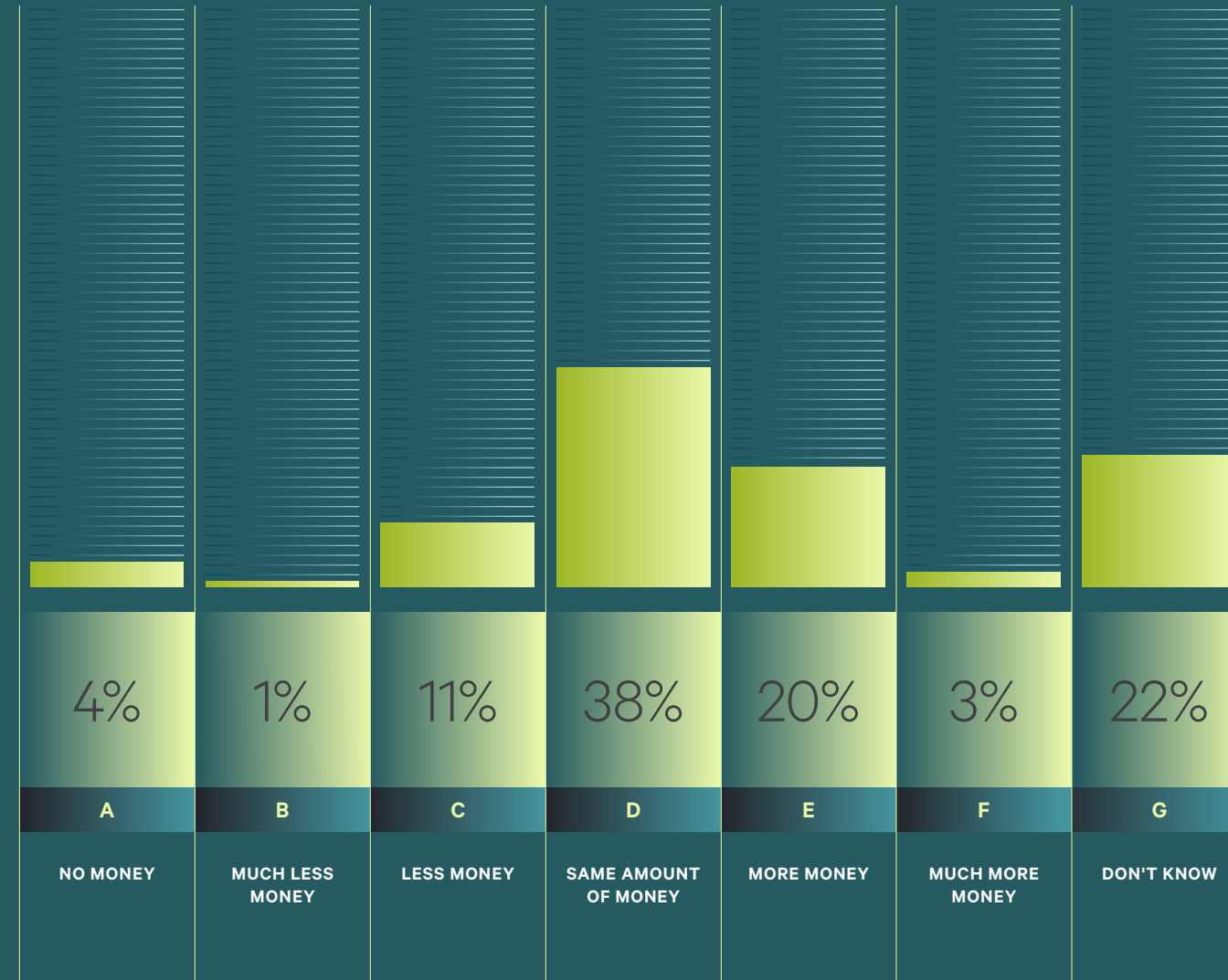
In the last budget planning process, Compliance received _____ for its work this year as compared to last year.

ANSWERS

(Absolute #s)

A	No money	5
B	Much less money	1
C	Less money	13
D	Same amount of money	45
E	More money	24
F	Much more money	4
G	Don't know	26

N=118



Q12

Which statement completes the sentence in a way that reflects how compliance is handled at your company?

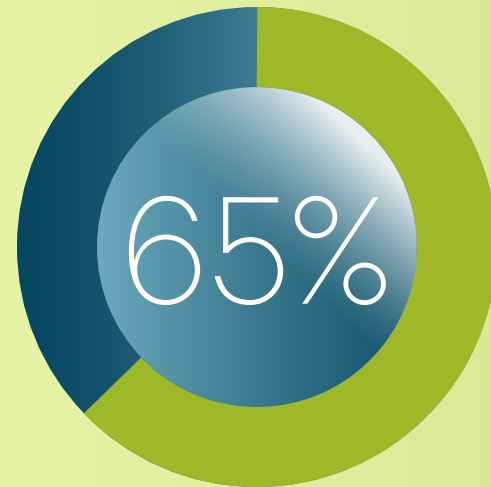
Our compliance operations are: _____.

ANSWERS

(Absolute #s)

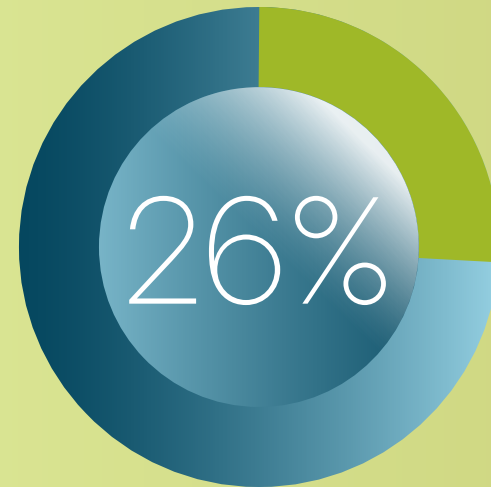
A	Mostly centralized in the compliance department	76
B	Mostly shared by the compliance department and other business departments	31
C	Mostly decentralized from the compliance department to other business departments	8
D	Don't know	2

N=117



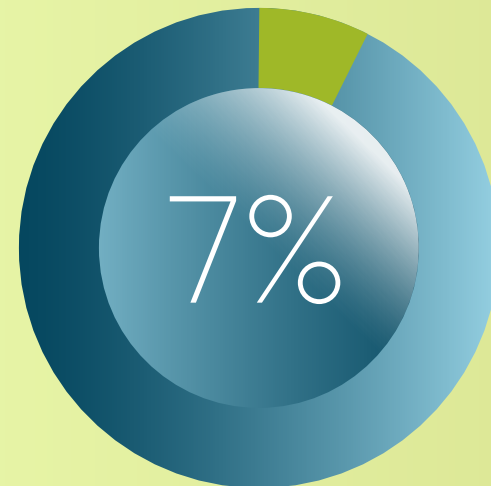
A

MOSTLY CENTRALIZED IN THE COMPLIANCE DEPARTMENT



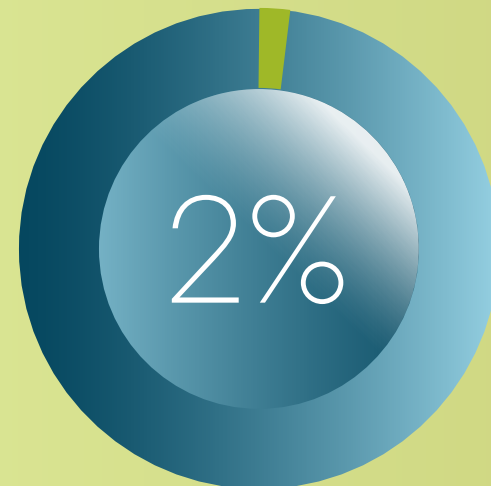
B

MOSTLY SHARED BY THE COMPLIANCE DEPARTMENT AND OTHER BUSINESS DEPARTMENTS



C

MOSTLY DECENTRALIZED FROM THE COMPLIANCE DEPARTMENT TO OTHER BUSINESS DEPARTMENTS



D

DON'T KNOW

Q13

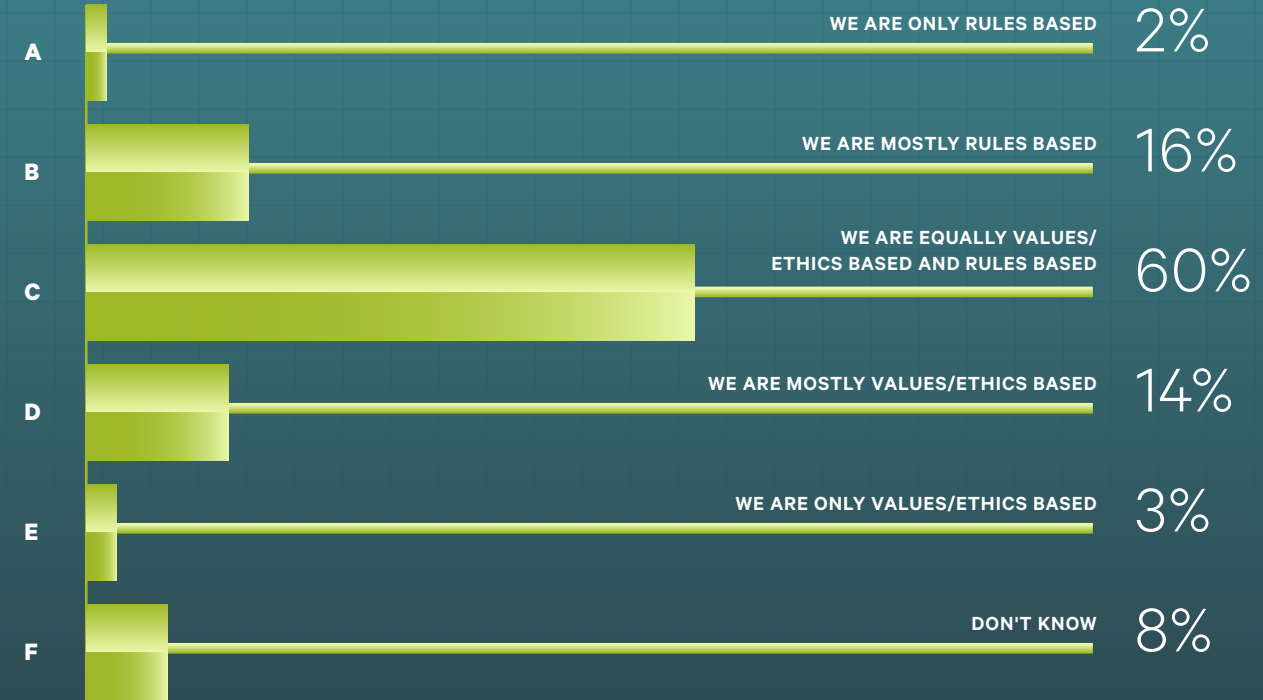
Which statement best describes the design of your company's healthcare compliance program?

ANSWERS

(Absolute #s)

A	We are only rules based	2
B	We are mostly rules based	16
C	We are equally values/ethics based and rules based	70
D	We are mostly values/ethics based	16
E	We are only values/ethics based	4
F	Don't know	9

N=117



Q14

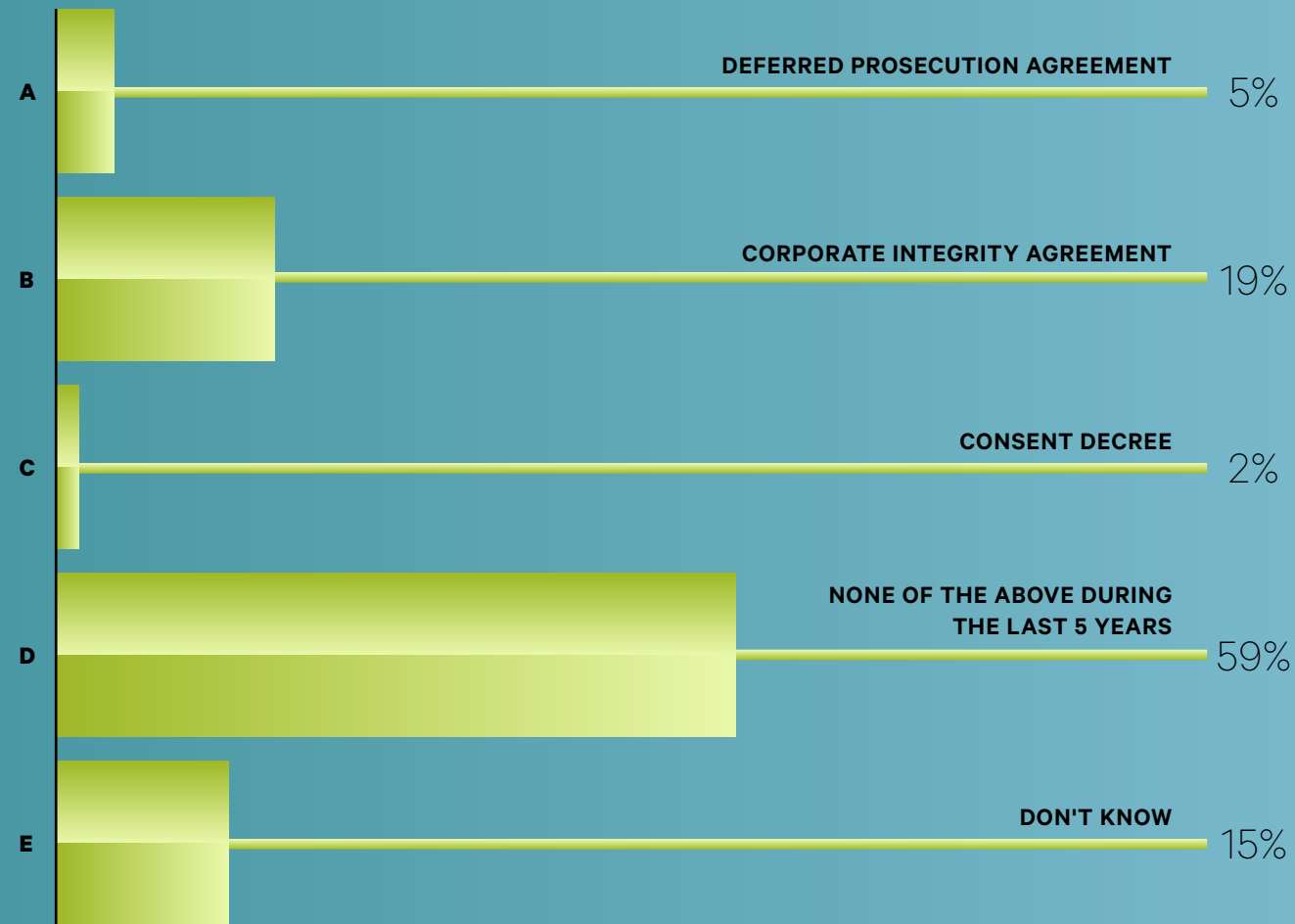
Identify any of the following that your company has operated under at any point during the last 5 years.

ANSWERS

(Absolute #s)

A	Deferred Prosecution Agreement	6
B	Corporate Integrity Agreement	22
C	Consent Decree	2
D	None of the above during the last 5 years	67
E	Don't know	17

N=114



Q15

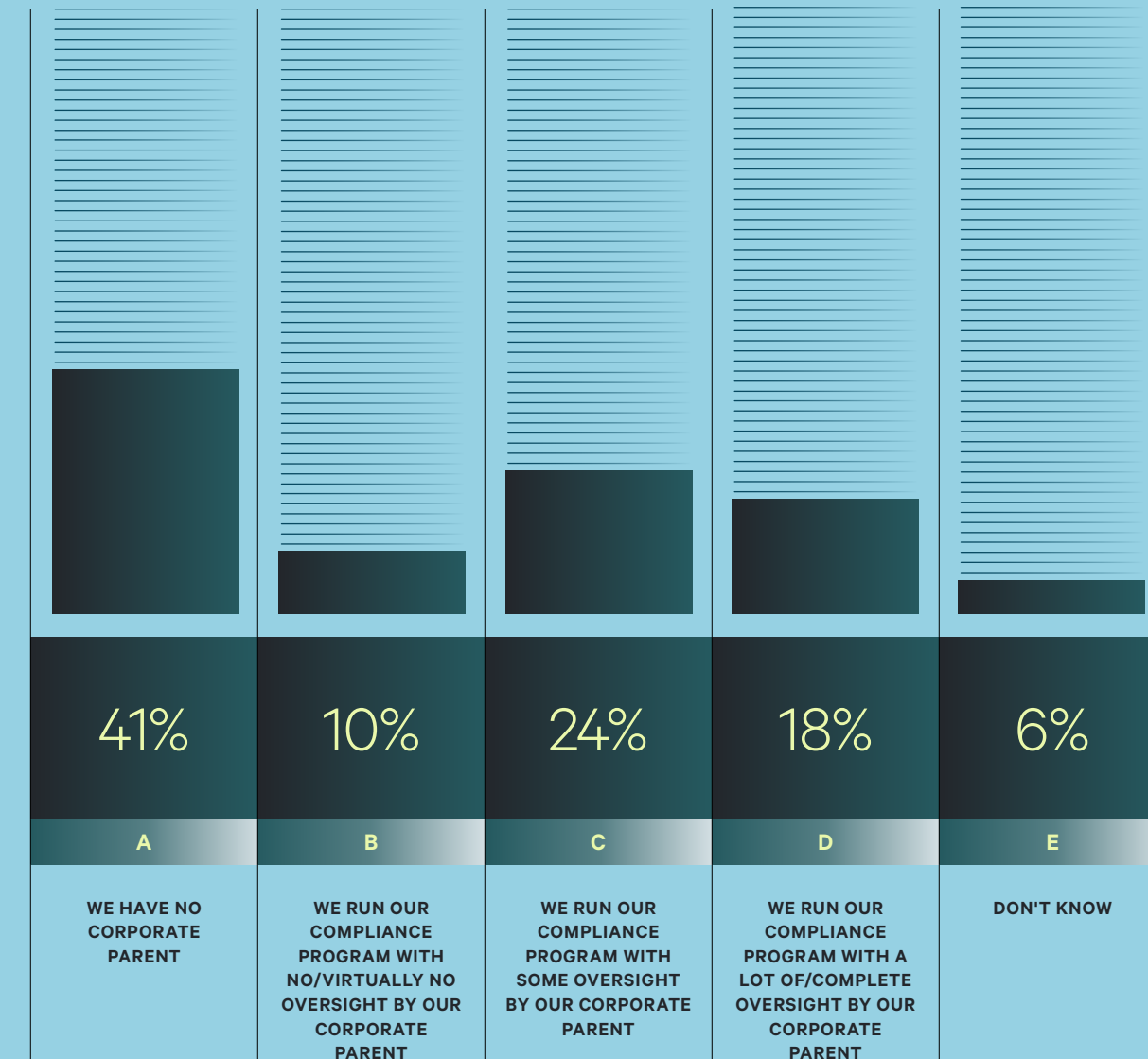
Which phrase best describes your company's healthcare compliance relationship with your corporate parent, i.e. a larger entity/company that owns you?

ANSWERS

(Absolute #s)

A	We have no corporate parent	47
B	We run our compliance program with no/virtually no oversight by our corporate parent	12
C	We run our compliance program with some oversight by our corporate parent	28
D	We run our compliance program with a lot of/complete oversight by our corporate parent	21
E	Don't know	7

N=115



Q16

Choose the statement that best describes the adherence to United States healthcare compliance laws, regulations and codes by companies in your industry.

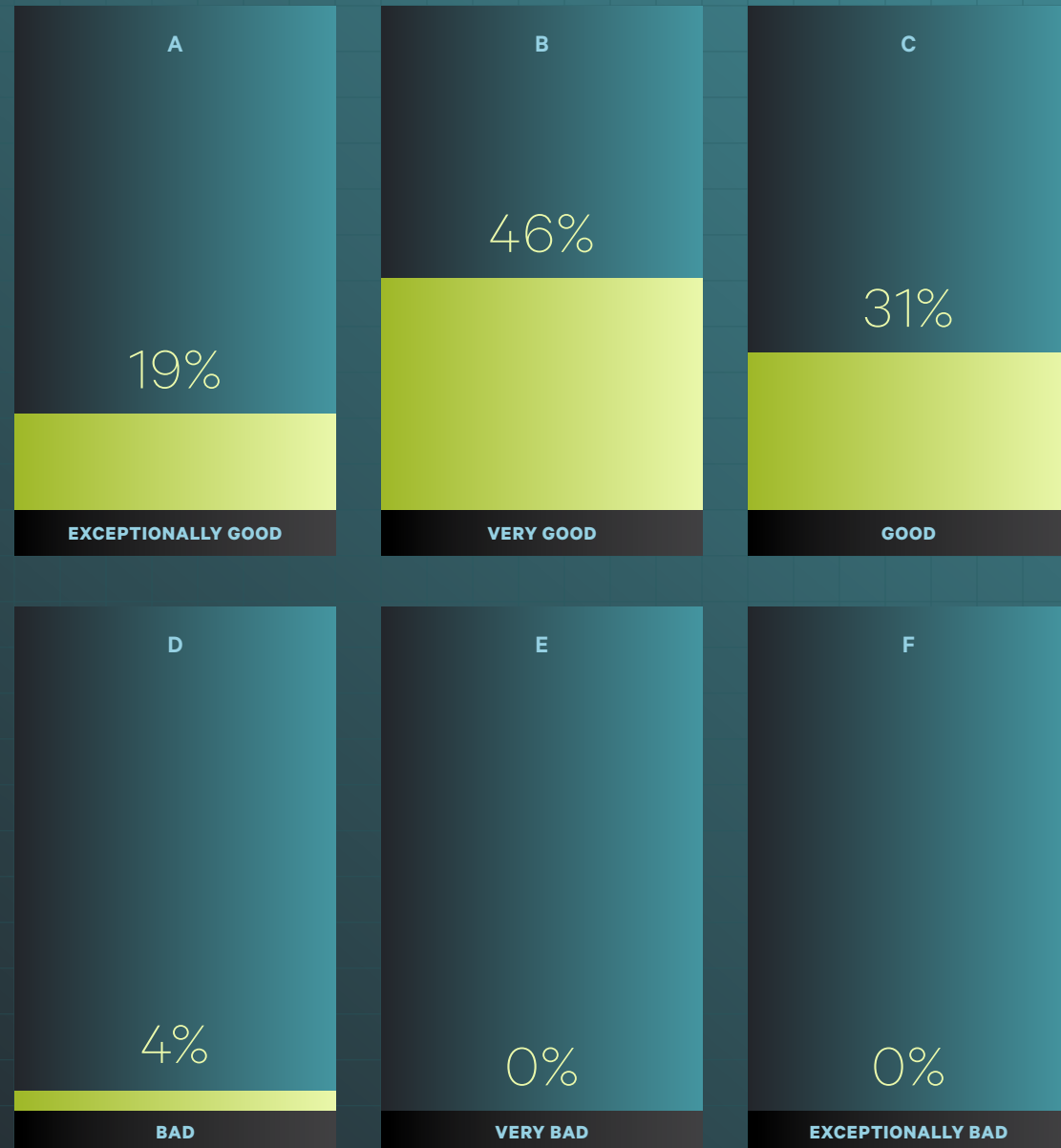


ANSWERS

(Absolute #s)

A	Exceptionally good	21
B	Very good	51
C	Good	34
D	Bad	4
E	Very bad	0
F	Exceptionally bad	0

N=110



Q17

Complete the following sentence with the statement that best describes your view.

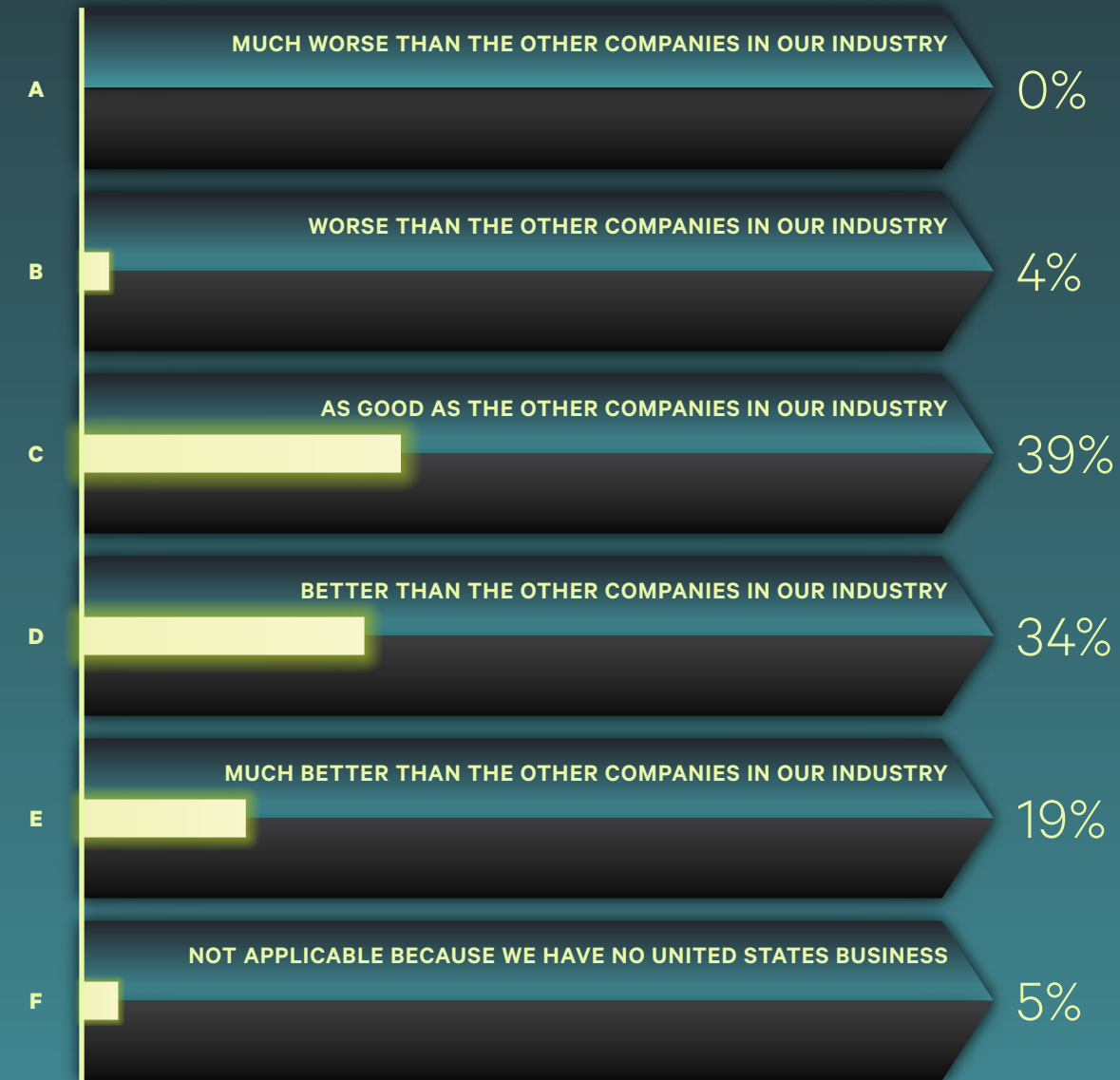
Our company's performance in meeting United States healthcare compliance obligations is: _____.

ANSWERS

(Absolute #s)

A	Much worse than the other companies in our industry	0
B	Worse than the other companies in our industry	4
C	As good as the other companies in our industry	42
D	Better than the other companies in our industry	37
E	Much better than the other companies in our industry	21
F	Not applicable because we have no United States business	5

N=109



Q18

Choose the statement that best describes the adherence to European healthcare compliance laws, regulations and codes by companies in your industry.



ANSWERS

(Absolute #s)

A	Exceptionally good	13
B	Very good	31
C	Good	56
D	Bad	2
E	Very bad	3
F	Exceptionally bad	0

N=105



Q19

Complete the following sentence with the statement that best describes your view.

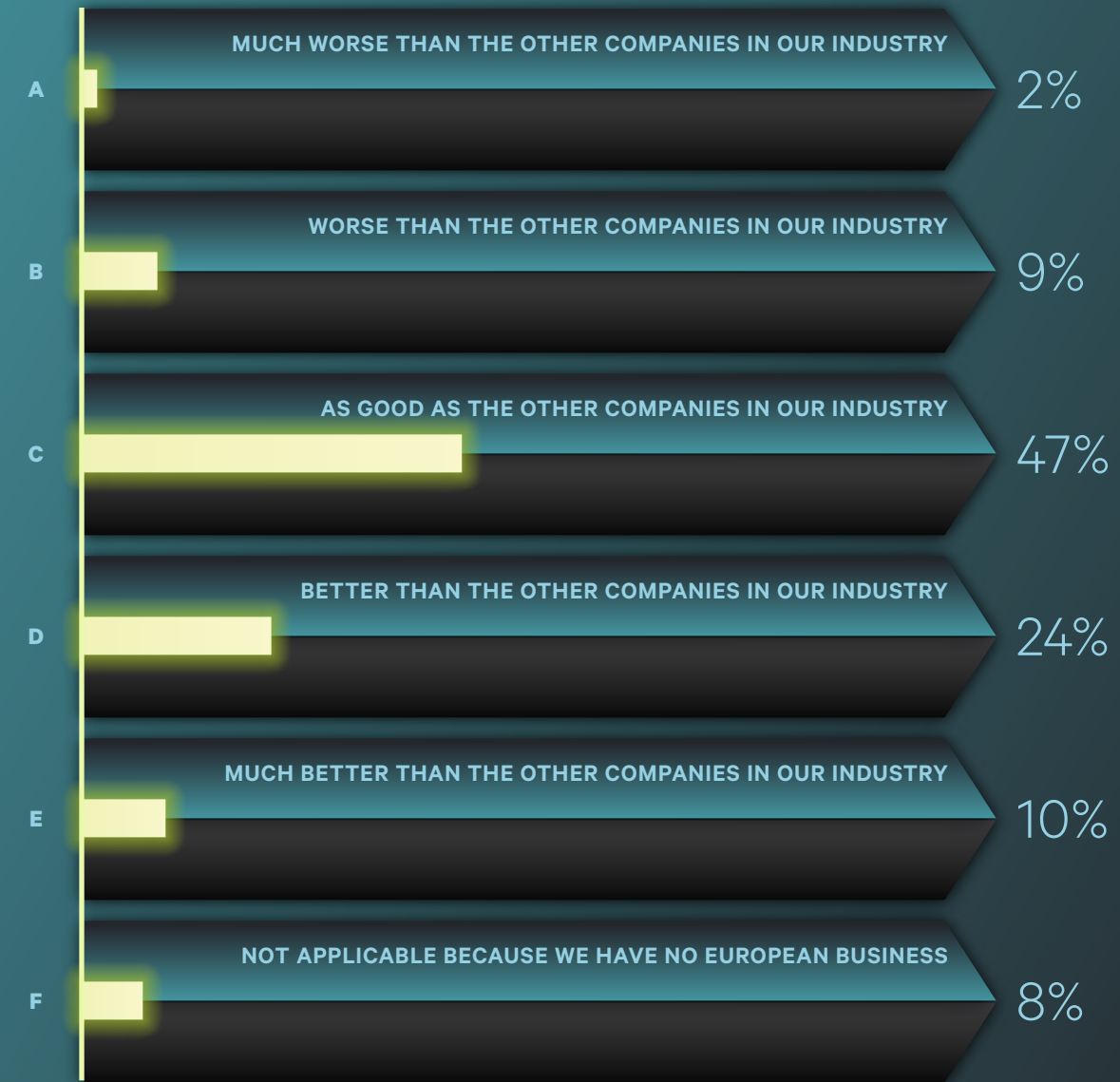
Our company's performance in meeting our European healthcare compliance obligations are: _____.

ANSWERS

(Absolute #s)

A	Much worse than the other companies in our industry	2
B	Worse than the other companies in our industry	10
C	As good as the other companies in our industry	50
D	Better than the other companies in our industry	25
E	Much better than the other companies in our industry	11
F	Not applicable because we have no European business	8

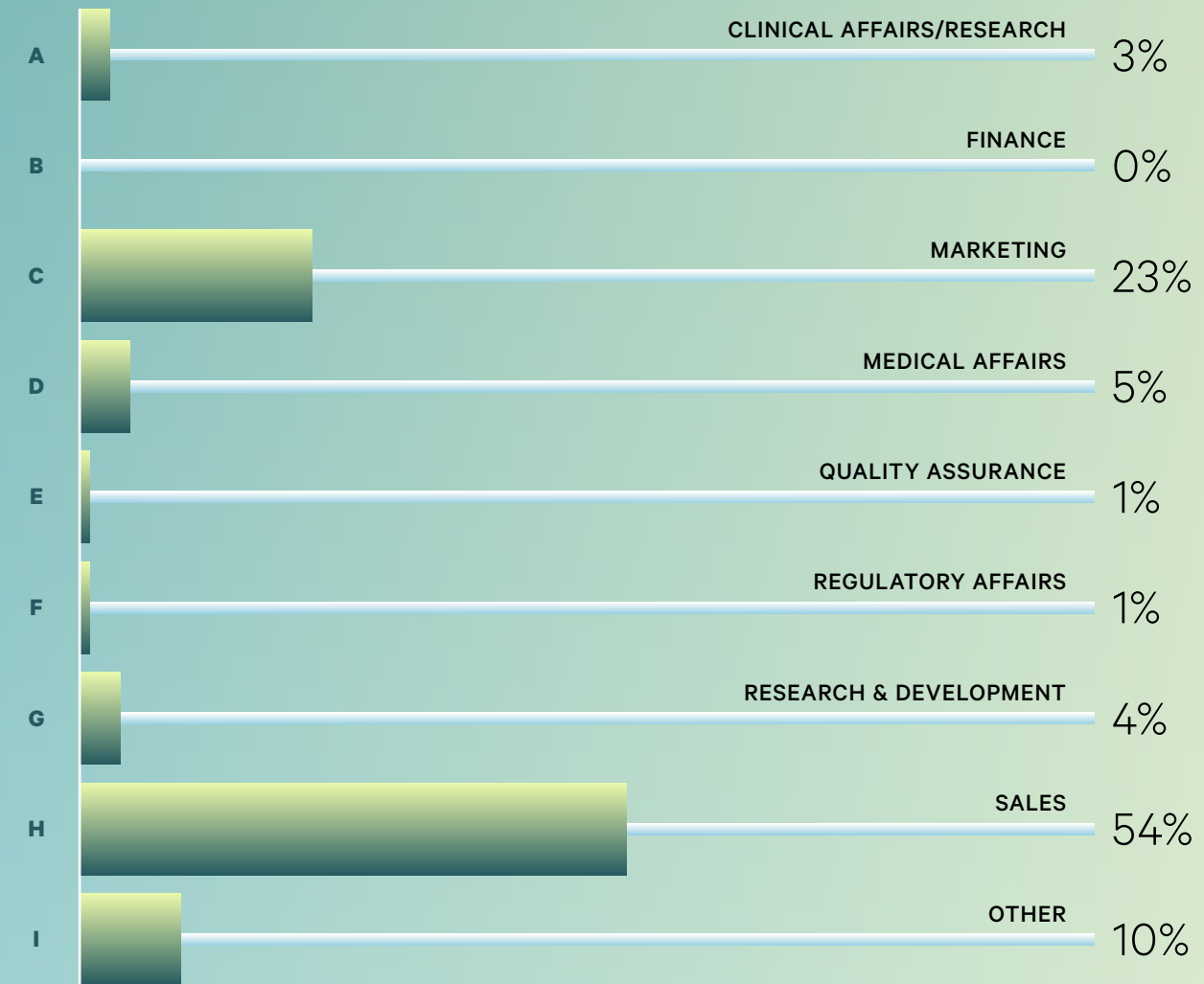
N=106



Q20

Complete the following sentence with the statement that best reflects your views:

In our industry, the department that most frequently has difficulties adhering to healthcare compliance laws and regulations is: _____.



ANSWERS

(Absolute #s)

A	Clinical Affairs/Research	3
B	Finance	0
C	Marketing	23
D	Medical Affairs	5
E	Quality Assurance	1
F	Regulatory Affairs	1
G	Research & Development	4
H	Sales	55
I	Other	10

N=102

Q20

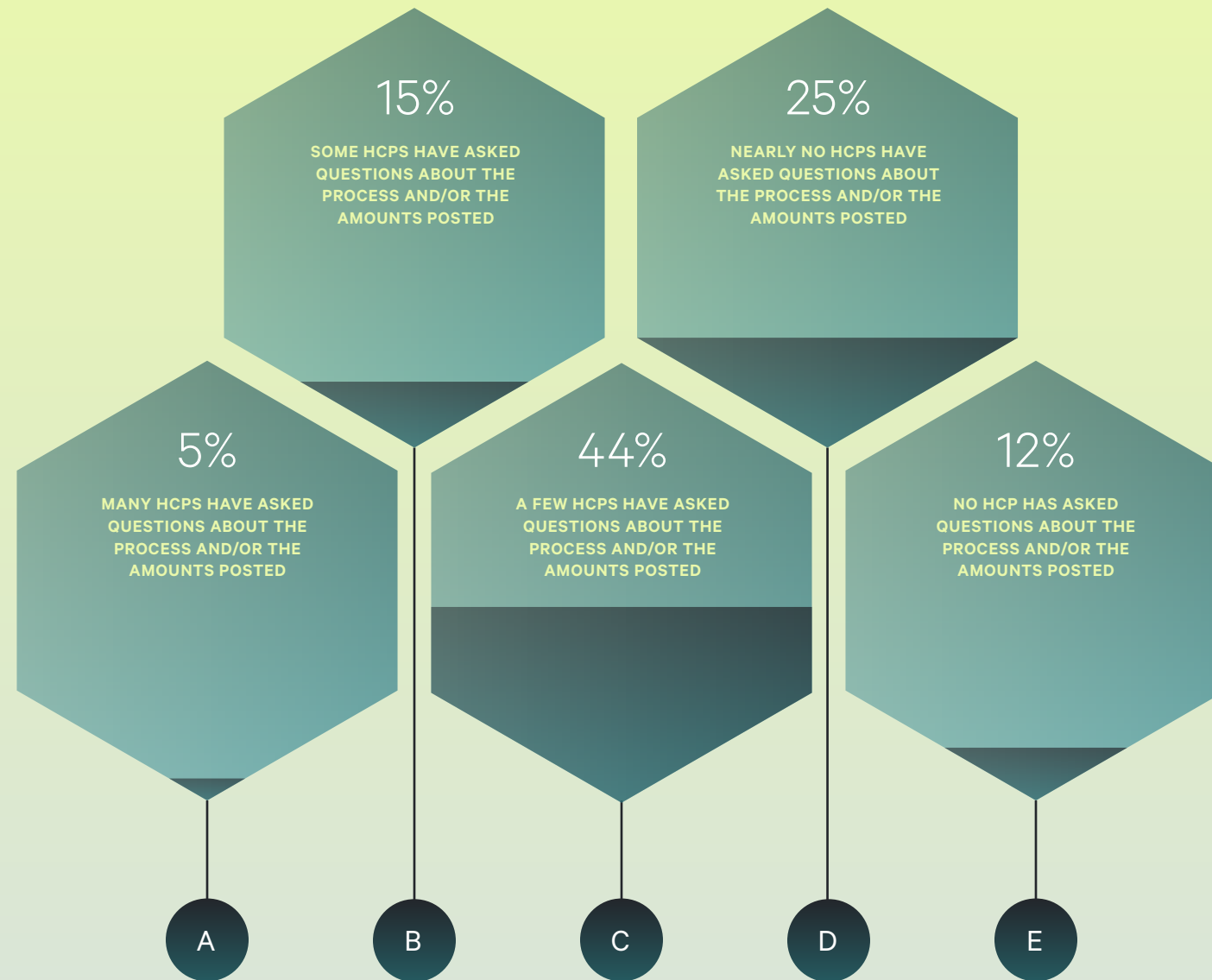
Which statement best describes how your HCP customers/consultants have reacted during the last reporting period to your collection/submission of HCP financial data to comply with the Sunshine Act/Open Payments?

ANSWERS

(Absolute #s)

A	Many HCPs have asked questions about the process and/or the amounts posted	5
B	Some HCPs have asked questions about the process and/or the amounts posted	15
C	A few HCPs have asked questions about the process and/or the amounts posted	45
D	Nearly no HCPs have asked questions about the process and/or the amounts posted	25
E	No HCP has asked questions about the process and/or the amounts posted	12

N=102



Q21

Which phrase below most accurately completes the following sentence?

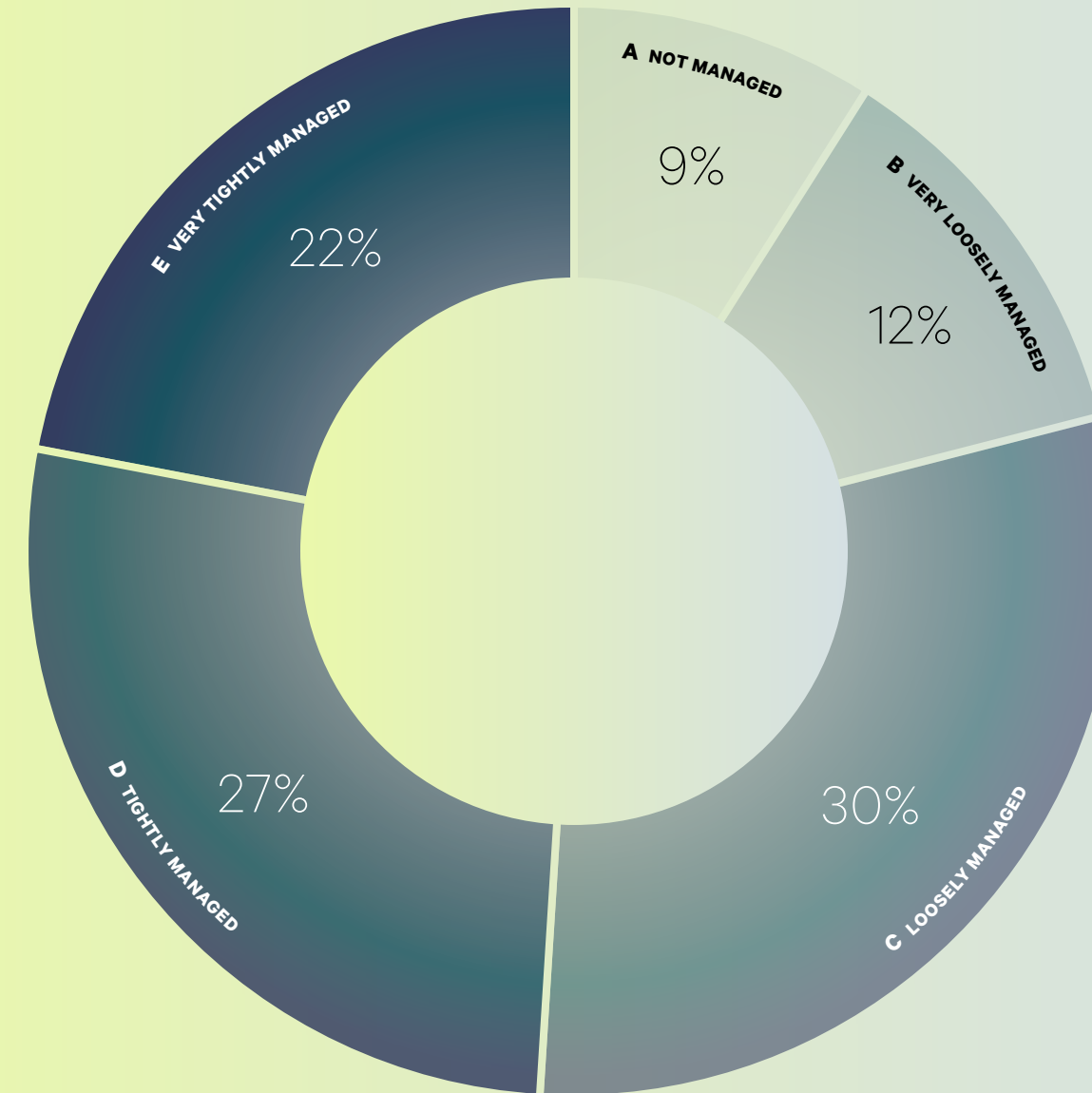
Social Media postings by our employees regarding the company's products are: _____.

ANSWERS

(Absolute #s)

A	Not managed	9
B	Very loosely managed	12
C	Loosely managed	30
D	Tightly managed	27
E	Very tightly managed	22

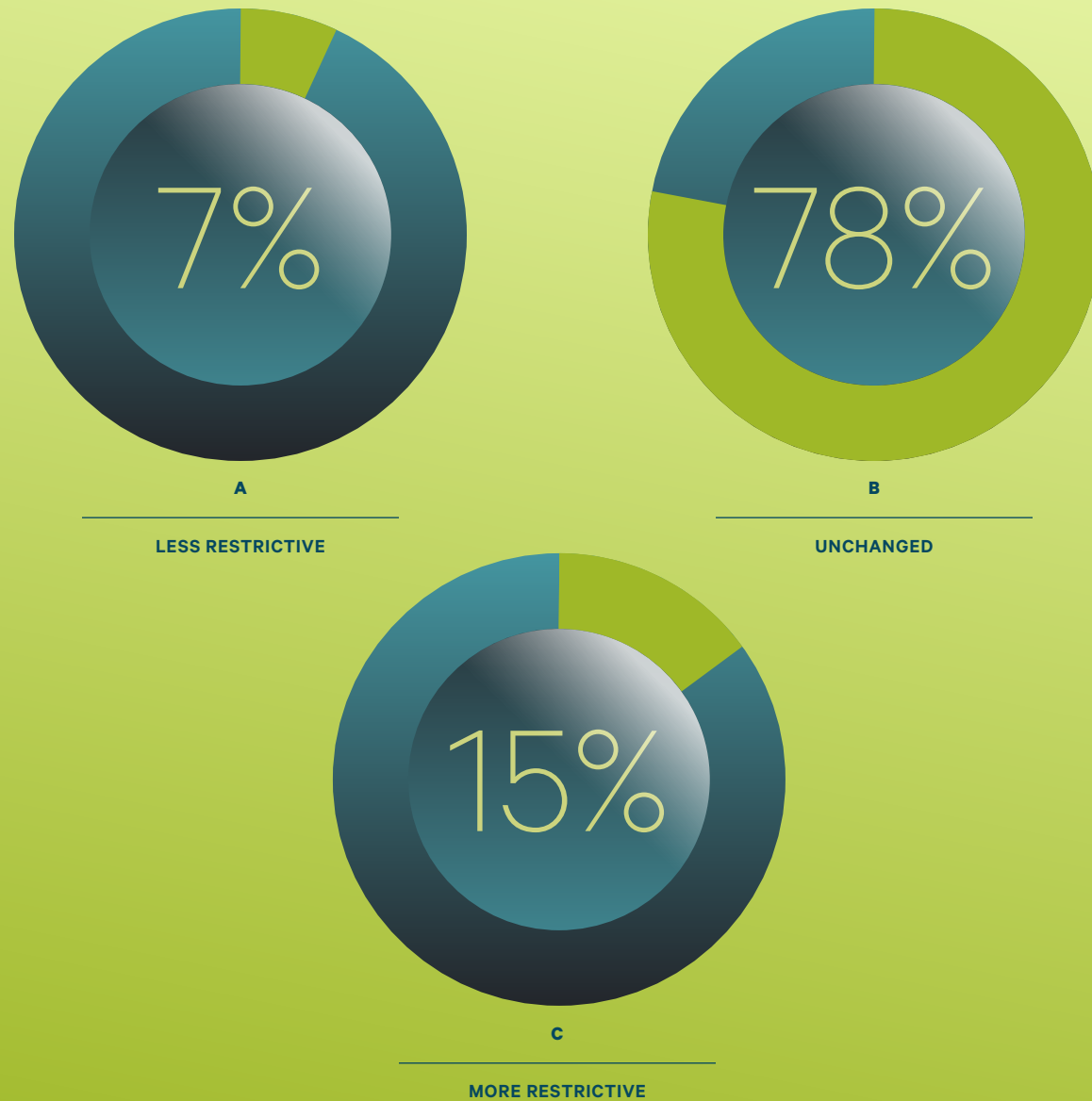
N=100



Q22

Which phrase best represents your company's approach?

Recent decisions by the courts and settlements with FDA associated with First Amendment rights have caused my company to be _____ in our approach to allowing salespeople to share information with healthcare professionals.



ANSWERS

(Absolute #s)

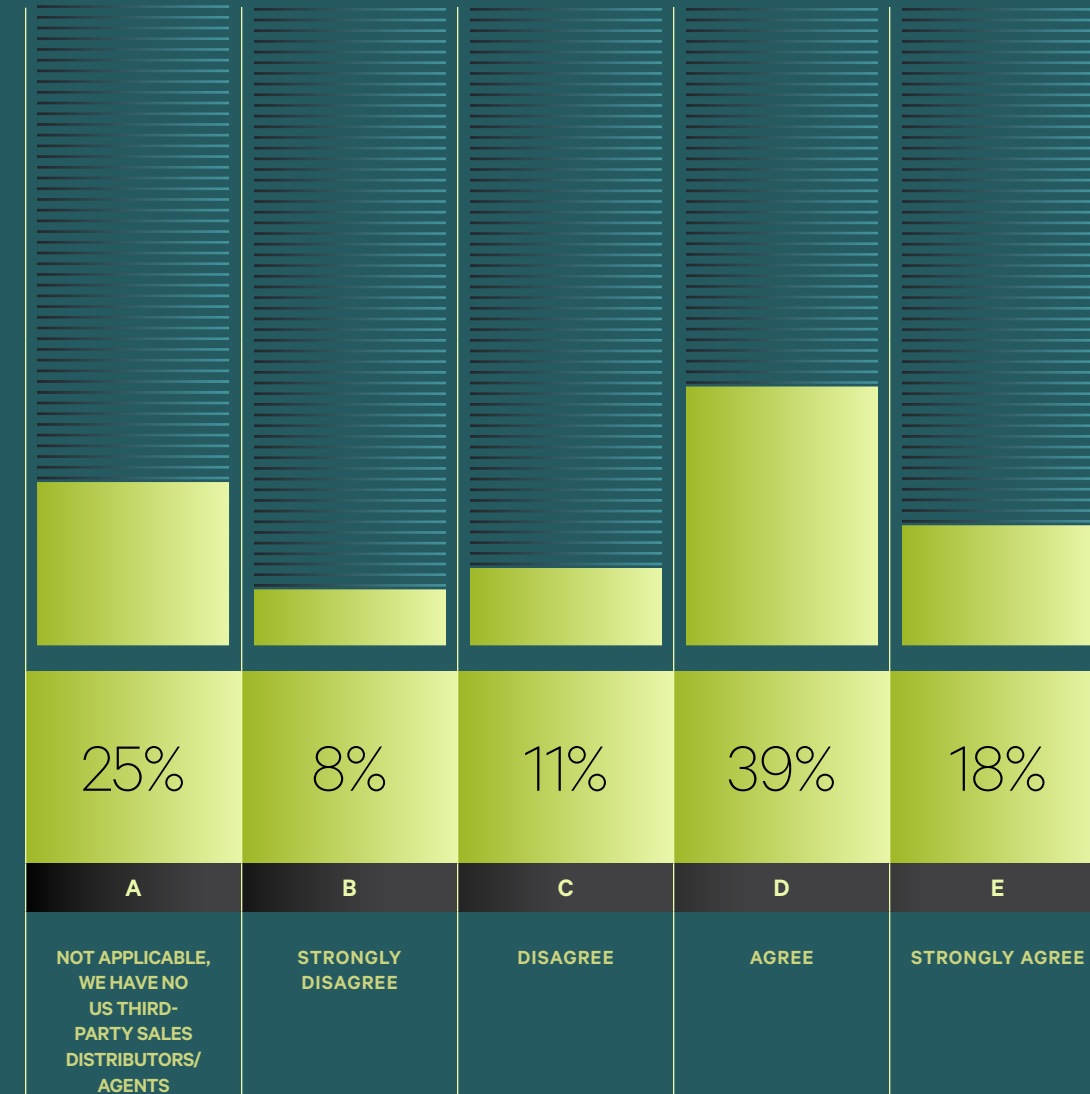
A	Less restrictive	7
B	Unchanged	77
C	More restrictive	15

N=99

Q23

Choose the statement below that reflects the degree to which you agree/disagree with the following statement:

Our company's United States third-party sales distributors/agents do meet the same healthcare compliance standards that the company has set for direct employees.



ANSWERS

(Absolute #s)

A	Not applicable, we have no US third-party sales distributors/agents	25
B	Strongly disagree	8
C	Disagree	11
D	Agree	39
E	Strongly agree	18

N=101

Q24

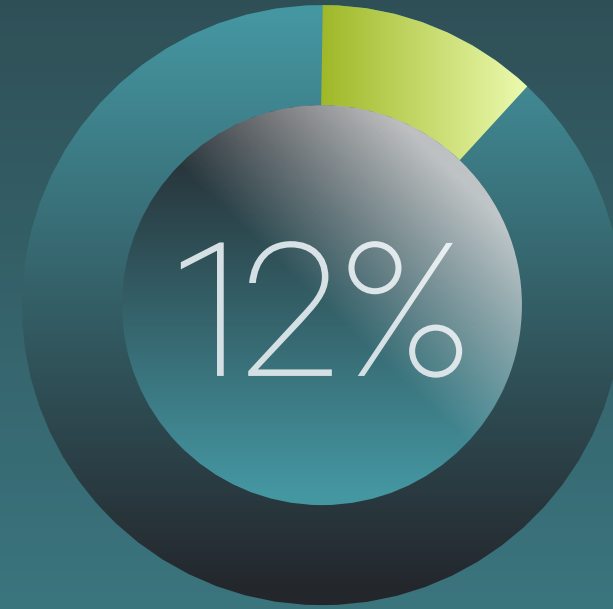
Complete the following sentence with the phrase that best reflects your views:

Regarding the future, I am _____ that healthcare compliance will have a positive impact on the behavior of the United States life sciences industry.



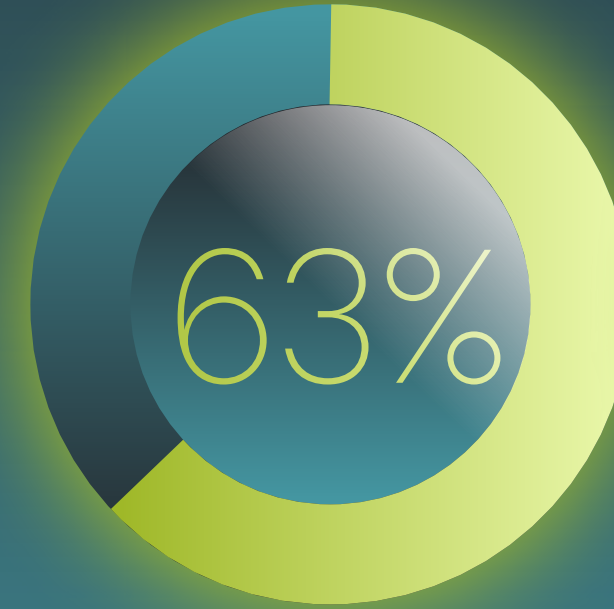
A

VERY DOUBTFUL



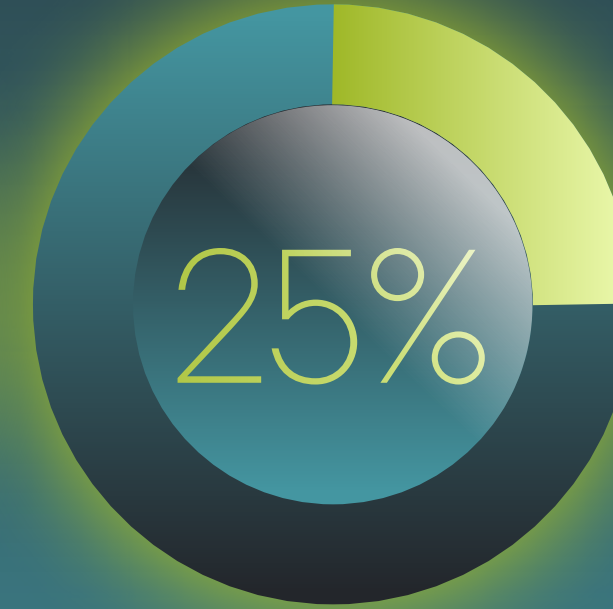
B

QUITE DOUBTFUL



C

QUITE CERTAIN



D

VERY CERTAIN

ANSWERS

(Absolute #s)

A	Very doubtful	0
B	Quite doubtful	11
C	Quite certain	58
D	Very certain	23

N=92



ABOUT PORZIO LIFE SCIENCES, LLC

Porzio Life Sciences helps companies keep advancing their business's goals while maintaining compliance with the complex, ever-changing demands of state, federal and global regulations.

PorzioLS helps pharmaceutical, medical device and biotechnology organizations through an array of innovative products and services designed to master the evolving regulatory environment.

PorzioLS is a wholly owned subsidiary of the law firm of Porzio, Bromberg & Newman P.C (Porzio). Porzio has provided regulatory counseling, risk management and litigation avoidance counseling to the life sciences industry for over 30 years.

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