White Paper

2020 U.S. TRENDS IN TRANSPARENCY REPORTING

Findings of IQVIA's 11th annual benchmarking survey

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Introduction

As befits a fast-paced, dynamic industry, the life sciences regulatory landscape is perpetually in flux. For the past 11 years, IQVIA has rigorously documented best practices in how pharmaceutical companies, medical device manufacturers and other industry firms collect and report data pertaining to HCP engagements.

The 2020 survey includes the perspectives of nearly 50 stakeholders at biotech, pharmaceutical and medical device manufacturers. The collection and analysis of their responses achieves the most comprehensive assessment available today of insights in compliance, reporting and relationship management controls and protocols. The granular level of insight into this data captures the trend lines across mission-critical activities within the promotional education and engagement spectrum.

INDUSTRY SNAPSHOT BY SIZE: SMALLER FIRMS PREDOMINATE

Pharmaceutical manufacturers comprised 56% of this year's survey respondents, and medical device manufacturers comprised an additional 33%. The remaining 11% of respondents were representatives of biotech firms.

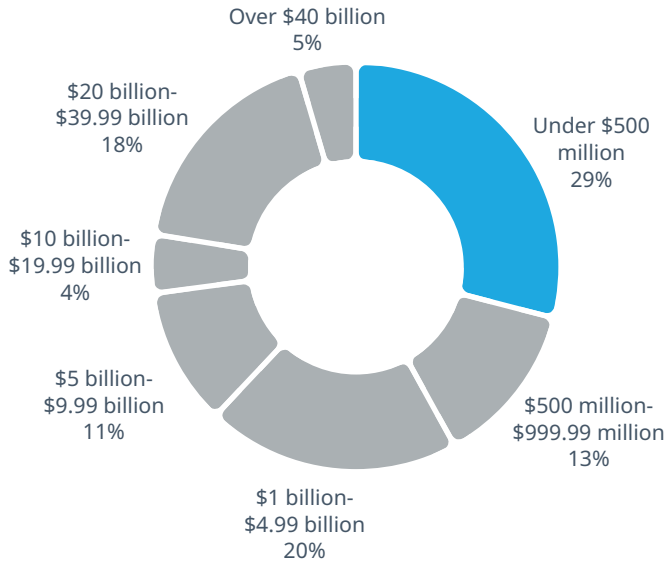
Figure 1: Primary business of respondents

Pharmaceutical Manufacturers | **Medical Device** | **Biotech**

Small firms were heavily represented in this year's survey, with 42% of respondents in the sub-$1B category: 29% of respondents reported annual revenue of less than $500MM and another 13% reported revenue of $500MM to $999.99MM. Mean revenue was $3.2B, in contrast to the 2019 survey, for which mean revenue was $3.95B.

In the 2020 survey, 5% of respondents had revenue greater than $40B; in 2019, the number of $40B+ firms comprised 12% of the total.

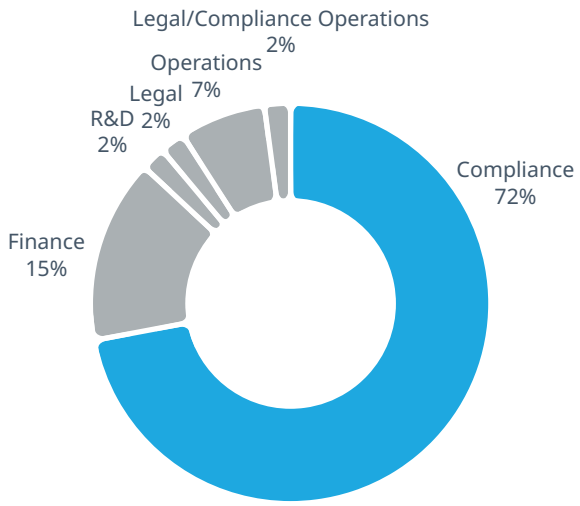
Figure 2: Revenue of respondents' companies



INDUSTRY SNAPSHOT BY RESPONDENT ROLES: SILOS CONTINUE TO EVOLVE

It is increasingly clear that compliance is approached as a cross-silo priority: Nearly three in four — 72% — of this year's respondents work in their respective firm's compliance departments, while 15% work in finance. The percentage of respondents who work in corporate finance fluctuates from year to year in IQVIA's survey. The remainder of the respondents in the 2020 survey worked in legal, operations and research and development.

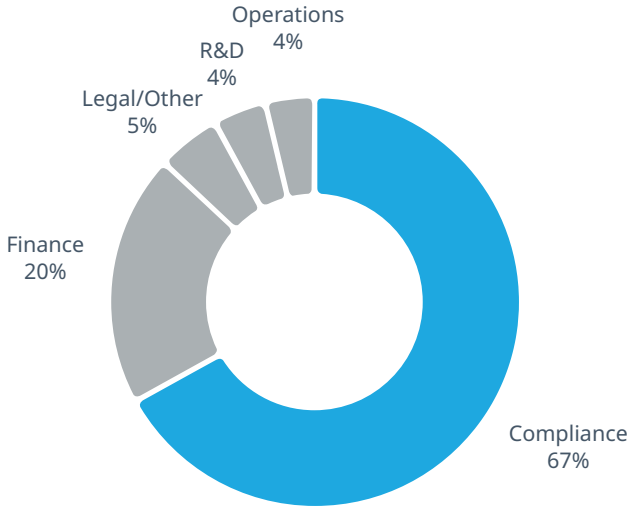
Figure 3: Department in which respondents work



Regardless of their department, these professionals are personally responsible for their company's transparency and disclosure compliance. A remarkable 96% of this year's respondents characterized themselves as "very involved" in ensuring their employer is compliant with transparency and disclosure requirements at the state, federal and global levels.

About two-thirds — 67% — of respondents report that gathering and aggregating transparency and disclosure reporting data is the responsibility of their compliance department, while 20% say this is the responsibility of their finance department and 4% each say it is a function performed by their R&D or operations department; the remaining respondents said this task is the role of their legal or chose "other" in response to the question.

Figure 4: Department responsible for transparency reporting

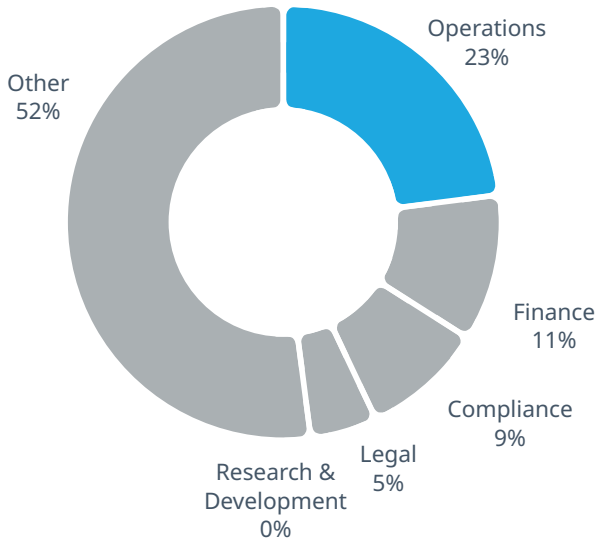


Among compliance-related functions with which this year's survey respondents are tasked, 89% say they are responsible for auditing and monitoring HCP interactions. 33% say their responsibility involves Bribery/Corruption/Foreign Corrupt Practices Act oversight, 26% say sourcing external funding streams like medical grants, IIS and charitable requests is their responsibility, and 11% say they are responsible for managing GDPR and data privacy compliance — including consent management. (Respondents could select more than one choice.)

One operational function that is scattered across a significant range of departments or silos is managing drug price transparency: 23% of respondents say this is the responsibility of their operations department, 11% say it is the purview of the finance department, 9% say it is the responsibility of the compliance department, 5%

say it is the responsibility of legal, and the remainder — 52% — chose "other" in response.

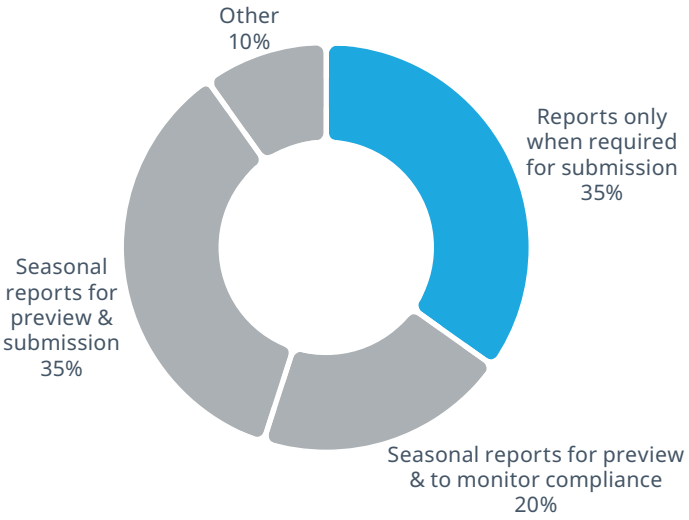
Figure 5: Department responsible for drug pricing



HOW COMPANIES ARE COMPLYING AND THE ROLE OF THIRD-PARTY SOLUTIONS

Life Sciences companies take a variety of approaches to their compliance requirements, and use a wide variety of tools to do so. Although, the penetration of turnkey solutions is lower than might be expected given the growing complexity of the requirements. Among this year's survey respondents, 35% generate reports only when required for submission. Another 35% generate reports seasonally for preview, as well as using the reports to monitor compliance. One in five — 20% — generate reports quarterly or on an otherwise seasonal basis for preview, then for submission. (The remaining 10% of respondents say another methodology best describes how their organization generates and uses reports.)

Figure 6: How reports are used



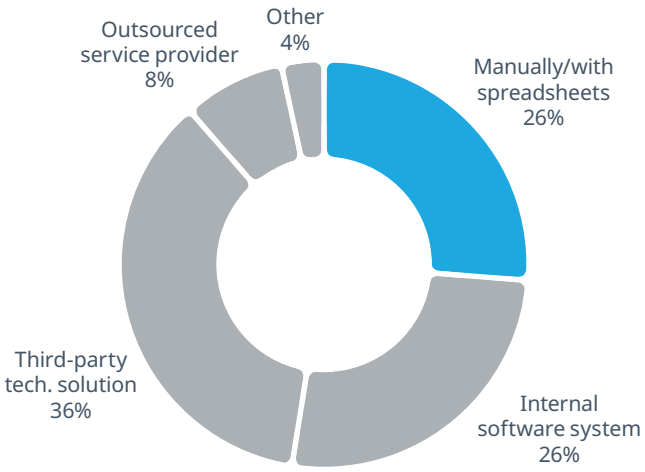
While 63% of respondents report that they use third-party technology solutions for managing transparency and disclosure compliance, a whopping 59% say they are also using spreadsheets to manually perform this critical task. (Respondents could select more than one option.) Slightly more than one third — 35% — use an internal software system and 11% use an outsourced service provider.

59% of respondents say they are also using spreadsheets to manually manage transparency and disclosure compliance.

For managing HCP consultant interactions and engagements activities such as onboarding, contract creation and management, 36% of respondents use a third-party technology solution. Another 26% use an

internal software system. 26% use spreadsheets, and 8% use an outsourced provider. (As with the previous question, respondents could choose more than one answer.)

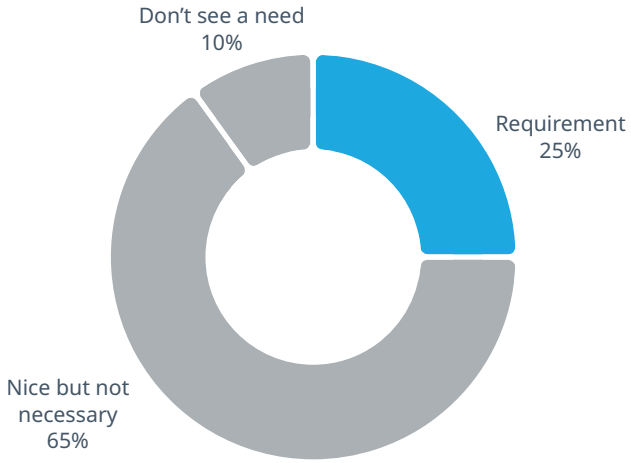
Figure 8: How HCP consultants are managed



PRIORITIES IN COMPLIANCE INFRASTRUCTURE INVESTMENTS

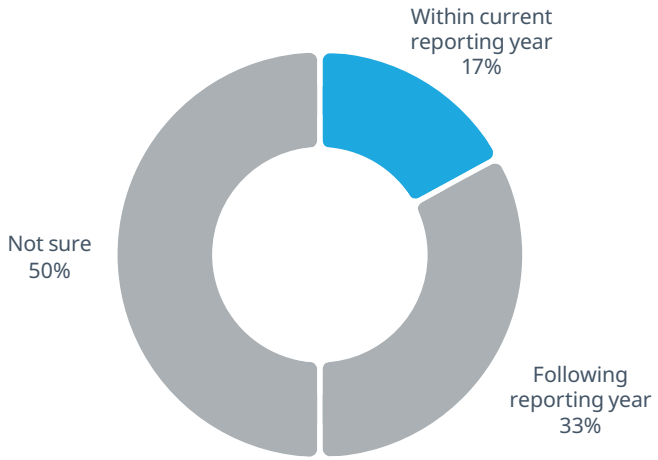
Despite the challenges of managing cross-platform compliance initiatives, only one in four respondents characterize having a single, end-to-end solution for managing HCP consultant engagements, HCO interactions and disclosure reporting, as "absolutely a requirement." A significant majority — 65% — say having an integrated, inclusive solution would be "nice" but not imperative, and the remaining 10% don't find it to be a high priority.

Figure 9: Importance of having an end-to-end solution



While slightly less than one third — 32% — say they are considering outsourcing to a third-party provider in the future, 68% are not currently considering outsourcing. Among those who are considering outsourcing in the future, timelines vary for those who are considering outsourcing to a third-party provider: 17% say it will be within the current reporting year and 33% say it will be in the following year; the remaining half of respondents chose "Not Sure" as an option.

Figure 10: Timeline for considering a third-party provider

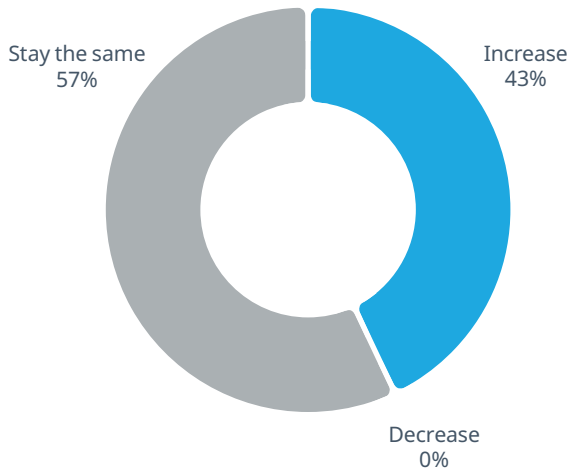


COSTS ON THE RISE AS GLOBAL COMPLIANCE LANDSCAPE EVOLVES

While companies might view turnkey solutions as a cost center, a snapshot of resource allocation indicates that many firms are accelerating their spending regardless: A mere 3% of respondents expect their employer's investment in solutions and resources to manage aggregate spend and disclosure reporting and compliance to decrease over the next year. Half said they expected this spending to remain the same, and the remaining 47% anticipate increases.

In terms of investment in drug pricing transparency reporting, not a single respondent expects that their employer's investment in solutions and resources will decrease over the next year. More than four in 10 — 43% — expect this investment to increase, while 57% expect it to remain the same.

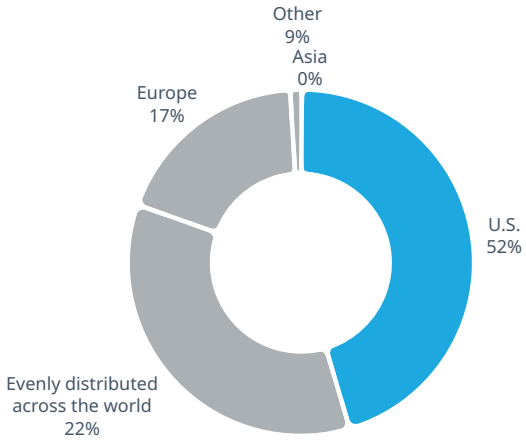
Figure 11: Anticipated investment in drug pricing



Respondents say regulatory requirements are overwhelmingly responsible for these increases, with 83% citing a combination of state, federal and global transparency and disclosure requirements driving the higher spending.

Much of this is driven by the United States' regulatory landscape: 52% of respondents plan to increase their investment in the U.S., while 22% cite global requirements, saying their investments are spread evenly throughout the world. The increase in the European Union of Sunshine Law-like regulations is becoming apparent, as well: 17% of respondents say they plan to increase investment in Europe.

Figure 12: Geographic areas of expected investment



GLOBAL PRIORITIES, SPEND DRIVEN BY REGULATION

It is clear that satisfying global regulatory requirements is a concern for many compliance professionals in the Life Sciences industry: A majority, 56% say that when evaluating third-party providers, they would prefer to use one that offers a global solution, while one in four seek a regional platform and 19% prefer country-specific tools.

Figure 13: Third-party solution preference

A global platform | **A regional platform** | **A country-specific platform**

Despite these stated preferences, 30% report satisfying transparency and disclosure reporting requirements outside the United States via the use of spreadsheets, while nearly as many — 29% — use third-party technology. 20% use an internal software platform, 7% rely on an outsourced service provider, while 14% use other options to manage global reporting.

30% of respondents report satisfying transparency and disclosure reporting requirements outside the United States via the use of spreadsheets.

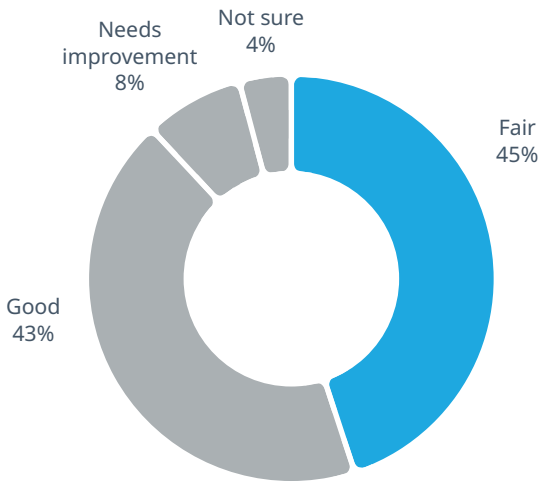
A strong majority — 84% — of respondents characterize auditing and monitoring HCP interactions as very important; 79% say compliance with bribery and corruption regulations and the Foreign Corrupt Practices Act are very important; 71% and 41%, respectively, say GDPR and data privacy compliance — including consent management — are very important. Slightly more than half — 54% — say compliance with the GDPR and associated regulations are "somewhat important."

IMPROVED VISIBILITY INTO COMPLIANCE IMPROVEMENT GOALS, CHALLENGES

This year's survey included, for the first time, an all-new tranche of process-management questions designed to better understand how pharmaceutical companies are utilizing their data and where they can leverage those compliance-related investments to better dovetail with the needs and priorities of their HCP and HCO stakeholders.

There is evidence of increased dissatisfaction on the part of respondents regarding the performance of their employers' current data capture and reporting processes. A plurality — 45% — characterize this performance as just "fair" and 8% say it needs improvement, compared to the 43% who say this performance is "good." The remaining respondents say they are not sure how well their approval and capture process functions. By comparison, a slim majority of 51% of respondents in 2019 said performance was good, 32% characterized it as fair and 7% said it needed improvement.

Figure 15: Performance of HCP consultant/HCO interactions and data capture process



Respondents have several ideas about what aspects of the HCP consultant/HCO interactions and data capture processes could be improved. These responses offer greater visibility into how compliance process managers can orient their protocols to better enhance the insights they obtain from their regulatory data management protocols.

More than one in four — 27% — of respondents want to enhance the integration processes connecting data capture to reporting, and a slightly smaller number — 23% — would like to see master data management pertaining to HCP, and HCP management/ licensure improved. (Note: respondents were allowed to select more than one option when answering this question.) One in five seek enhancements to approval workflows — inclusive of needs assessment, consultants, contracts, deliverables and other HCP/HCO touchpoints. 16% see a need to improve annual matching on data captured with no reference to MDM identifiers. Nearly the same number — 14% — seek to enhance their vendor management capabilities.

27% of respondents want to enhance the integration processes connecting data capture to reporting.

Based on the diversity of responses to this needs assessment query, it should perhaps not come as a surprise that many respondents report less-than-optimal standardization of data capture, aggregation and submission processes at their respective employers. While just over one in five — 21% — report that this process is very standardized and driven by SOPs, a majority — 55% — say that it is only somewhat standardized, reliant on best practices as well as SOP-driven protocols. Nearly one in four say the process is not SOP-driven or that they don't know how their protocols are derived.

DRIVING ROI BY LEVERAGING DATA, APPLYING ANALYTICS

Respondents to this year's survey are taking advantage of some of the aggregate spend data they generate to gain additional business and compliance insights, but many could leverage these insights to a greater degree than they are currently are: While 41% say they are utilizing the insights gleaned from this data at both global and regional or local levels, 44%, say they only use this data at the local or regional level, and 15% don't make use of this data at all outside of reporting requirements. Just over three in four — 76% — say they are using this data for both business analytics as well as compliance analytics.

Respondents leveraging internal aggregate spend data for compliance analytics have well-defined goals: Three in four target auditing, monitoring, and field force ride assessments; 72% provide this comparative data to compliance committees; 69% use it to inform quarterly compliance communications and trainings, and 63% deploy it in their development of Key Risk Indicators (KRIs).

Among other data assets survey respondents use for their compliance analytics, the most common are auditing and monitoring data, used by 56% of respondents. Industry-reported aggregate spend data such as the CMS Open Payments, MA, EFPIA, and similar databases, are used by 53% of respondents.

Nearly six in 10 — 58% — of respondents using the data for business analytics are using that information to gain greater insight into commercial effectiveness, and 58% are using it to glean Key Opinion Leader (KOL) metrics.

(Respondents could choose more than one answer to the question.) More than two in five — 42% — are leveraging the data for improved resource allocation, or plan to do so, and 27% use or plan to use the data to identify HCPs/HCOs for spend redistribution.

58% of respondents that are using the data for business analytics, leverage the information to gain greater insight into commercial effectiveness, and to glean Key Opinion Leader (KOL) metrics.

Conclusion

The growing awareness of shifting regulatory dynamics, and how analytics can be applied to data companies, already point towards a climate in which compliance can better drive efficiency—maximizing resource deployment. Since IQVIA launched this groundbreaking survey, the global regulatory climate has become much more complex, demanding increasingly resource-intensive management of transparency reporting obligations — particularly because much of this critical work is still being executed across silos rather than at an enterprise-wide scale.

IQVIA's landmark analytical capabilities provide an unparalleled degree of visibility into how regulatory requirements shape the practices and processes around promotional engagement activities. This report identifies information that companies can leverage to facilitate their strategic initiatives and optimize their operations around transparency reporting.

IQVIA Commercial Compliance leverages the industry's leading technologies to deliver streamlined processes and business efficiencies—with embedded compliance. From automating and managing the entire HCP/O engagement lifecycle, to capturing, collecting, and reporting global and local spend; to delivering strategy and planning support for live and virtual events—discover how IQVIA can help you with your commercial compliance needs. To learn more, email commercialcompliance@iqvia.com.

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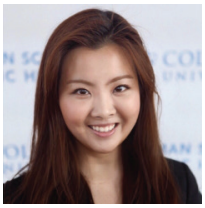
Johan Holm has over 14 years of global Pharma, Biotech and Med Device commercial compliance experience, and he currently leads the US Transparency Managed Services group within IQVIA Commercial Compliance. He has led a number of key engagements covering business-process improvement, cost-reduction and ROI enhancement across HCP promotional programs and transparency. Johan graduated from Babson College with a BS in Business Administration.



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Justin is an accomplished life sciences compliance leader with over 12 years of diverse industry and consultancy experience developing, implementing and leading strategic compliance programs. Justin joined IQVIA from Arthrex, Inc. where he was the Regional Compliance Officer for North America and EMEA regions. Prior to Arthrex, Justin was the Regional Compliance Officer for the Americas at BioMerieux, Inc. Justin also spent several years with PwC assisting a diverse set of clients in the area of healthcare corporate compliance. Leading up to PwC he held several roles of increasing responsibility with AstraZeneca in global compliance commercial audit and internal audit. Justin holds a Graduate Certificate in Healthcare Compliance from George Washington University, a Juris Doctorate from Widener University School of Law, and a Bachelor of Science in Accounting from Saint Joseph's University.

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