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Excellence and equity: From pilot to program, a Pfizer experience

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Abstract In 2021, Pfizer global regulatory affairs colleagues piloted an advanced pharmacy practice experience program as part of a company-wide diversity, inclusion, and equity program in collaboration with Howard University College of Pharmacy (CoP), a US-based historically Black college/university (HBCU).[1] Following pilot success, the initiative was elevated to full program status and the prospective student pool was expanded to include all HBCU CoPs in the US, as well as one predominantly Black institution. Selected students were placed under the supervision of volunteer Pfizer colleagues at the director level and above, and across different therapeutic areas and categories.

Keywords – equity, excellence, global regulatory affairs, historically Black college/university, predominantly Black institution, talent pipeline development, experiential education

Introduction

Excellence and equity are core values that define Pfizer's company culture to develop breakthroughs that change patients' lives. Both values underpin the need to achieve transformative patient outcomes in teams in which every member is seen, heard, and cared for. These goals are actioned through the Pfizer enterprise-wide three-pillar diversity, equity, and inclusion (DEI) strategy (**Figure 1**).

Figure 1. Pfizer's DEI strategy – Three strategic pillars

CoP, college of pharmacy; **GRA,** global regulatory affairs; **HBCU,** historically Black college/university; **HUCOP,** Howard University College of Pharmacy; **PBI,** predominantly Black institution.

Source: Pfizer

In alignment with the overall DEI strategy, particularly pillars 1 and 3, colleagues in Pfizer's global regulatory affairs division (GRA) identified HBCUs and predominantly Black institution CoPs as potential partners to support the mission of encouraging careers in regulatory affairs among diverse and talented students. HBCUs are defined under Title III of the Higher Education Act of 1965 by the US Congress as schools of higher learning that were accredited and established before 1964 and whose principal mission is the education of African Americans.[2] Of the more than 100 HBCUs across the US, those with accredited CoPs educate a significant percentage of pharmacy students identifying as underrepresented people of color (UPOC) nationwide. Although HBCU CoPs represent only 3%-4% of the total number of pharmacy schools in the US, they have consistently enrolled a larger percentage of UPOC students compared with all pharmacy schools nationwide. From 2015-2019, this included enrollment of 22.8% of African American students, 6.6% of American Indian and Alaska Native students, and 2% of Native Hawaiian and other Pacific Islander students.[3]

Predominantly Black institutions (PBIs) are also classified and defined by the US Congress. Under the Higher Education Opportunity Act of 2008, the bill that reauthorized the Higher Education Act of 1965, the key goal of PBIs is to expand higher education opportunities for eligible Black American and first-generation college students.[2,4] At least 50% of the students who matriculate at these institutions are low-income (i.e., individuals from a family whose taxable income

for the preceding year did not exceed 150% of an amount equal to the poverty level determined using the criteria of poverty established by the Bureau of the Census) or first-generation (i.e., individuals whose parents did not complete a baccalaureate degree).[5] Of all students enrolled at a PBI, 40% or more are African American.[5]

Pfizer GRA-HUCOP Pilot Program

The Pfizer GRA-Advanced Pharmacy Practice Experience (APPE) Pilot Program was initiated in 2021 in collaboration with Howard University COP (HUCOP), a top-ranked HBCU. A number of unique elements were built into the pilot design and implementation strategy to enhance the overall value of the experience. Unlike any other program at Pfizer, the pilot was intentionally focused on graduate-level doctor of pharmacy (PharmD) candidates from diverse backgrounds and with a strong interest in clinical research and regulatory science as evidenced by their prior experiences. In addition, the pilot experience was completely remote and delivered in a virtual format to allow for students from across the nation to participate without the financial burden of short-term physical relocation near a Pfizer campus.

Selected fourth-year HUCOP students with previous industry and/or health authority (e.g., US Food and Drug Administration [FDA]) externship experience enrolled in the pilot program and attained academic credit toward completion of the PharmD curriculum. Following graduation, each student gained employment with a Fortune 500 multinational, biopharmaceutical company in regulatory strategy and medical affairs functional roles. One student was hired as a full-time Pfizer colleague and is currently working in the GRA-Internal Medicine group as an above-country, regional regulatory strategist.

Expansion from pilot to program

Following the successful pilot in 2021 with HUCOP, the Pfizer GRA leadership team endorsed expansion to a full program with the opportunity to include students from additional HBCU and PBI CoPs.

To support this effort, Pfizer GRA colleagues worked closely with members of the Pfizer Global Black Community (GBC) Colleague Resource Group (CRG) and reviewed literature to identify all accredited HBCU and predominantly Black university PharmD programs that could incorporate biopharmaceutical experiential student opportunities into their curriculum. A total of seven institutions were identified, including all six HBCU CoPs (Florida Agricultural and Mechanical University, Hampton University, Howard University, Texas Southern University, University of Maryland Eastern Shore, and Xavier University) and one predominantly Black CoP (Chicago State University; **Table 1,** p. 4). Each institution provides an educational learning environment that caters to the unique experience of minority students. They serve as premier incubators for the development of African American science, technology, engineering, mathematics (STEM) professionals across the nation.[6,7] They rank among the highest producers of Black professionals in medicine and pharmacy.

Continued on p. 5

Table 1. HBCU and predominantly Black CoP profiles

HBCU/CoP	Profile
Chicago State University[8]	CSU is a predominantly Black public university in Chicago, Illinois. Its CoP embraces the overall mission to educate individuals from diverse backgrounds to enhance culturally competent care and reduce healthcare disparities. The CoP commitments include recruiting, retaining, and graduating student pharmacists from diverse populations and offering a curriculum that cultivates analytical thinking, ethical reasoning-and decision-making, intellectual curiosity, multidisciplinary and inter-professional collaboration, professionalism, and service.
Florida Agricultural & Mechanical University[9]	FAMU is a public, historically Black, land-grant university in Tallahassee, Florida. It is the third largest historically Black university in the US by enrollment and the only public historically Black university in Florida. It is ranked the number 1 HBCU for research and development by the National Science Foundation. The university continues its historic mission of educating African American students. The mission of the College of Pharmacy and Pharmaceutical Sciences, Institute of Public Health, in concert with FAMU, is to transform lives through the advancement of health and wellness of all populations, with a special emphasis on the health equity of vulnerable and underserved populations.
Hampton University[10]	A private, historically Black, research university in Hampton, Virginia. Hampton serves students from diverse national, cultural, and economic backgrounds. The institution has enrolled students from five continents – North America, South America, Africa, Asia, and Europe – including countries such as Gabon, Kenya, Ghana, Japan, China, Armenia, Great Britain, and Russia, as well as the Hawaiian and Caribbean Islands and numerous American Indian nations.
Howard University[11,12]	A private, federally chartered historically Black research university in Washington, DC. Howard is a leader in STEM fields. The National Science Foundation has ranked it the top producer of African American undergraduates who later earn science and engineering doctoral degrees. The mission of HUCOP is to provide pharmacy education of excellent quality to students with high academic, scholarship, and leadership potential, with particular emphasis on the recruitment, retention, and graduation of promising African American and other ethnically diverse minority students
Texas Southern University[13,14]	A public historically Black university in Houston, Texas. The university is one of the largest and most comprehensive historically Black colleges or universities in the US. It is a student-centered, comprehensive doctoral university committed to ensuring equality, offering innovative programs that are responsive to global challenges, and transforming diverse students into lifelong learners, engaged citizens, and creative leaders. The mission of the university's College of Pharmacy and Health Sciences is to provide quality academic programming to produce an ethnically diverse population of health professionals, especially African Americans and underrepresented minorities, who are transformational leaders in the delivery of interdisciplinary health services while addressing critical and urban issues.

Table 1 continued on p. 5

CoP, college of pharmacy; **HBCU,** historically Black college/university; **PharmD,** doctor of pharmacy; **STEM,** science, technology, engineering, and mathematics.

Table 1, *continued*. HBCU and predominantly Black CoP profiles

HBCU/CoP	Profile
University of Maryland Eastern Shore[15,16]	A public, historically Black land-grant research university in Princess Anne, Maryland. UMES provides individuals, especially first-generation students, access to a holistic learning environment that fosters multicultural diversity, academic success, and intellectual and social growth. UMES's School of Pharmacy is dedicated to developing exemplary pharmacy professionals and scholars who are committed to patient-centered care, lifelong learning, discovery, and service for diverse communities of the Delmarva Peninsula, the state of Maryland, and globally.
Xavier University[17,18]	A private, historically Black, Catholic university in New Orleans, Louisiana. Xavier is the only Catholic HBCU. It embraces a special mission to serve the African American Catholic community. Today, 75% of its enrollment is African American/Black and 12% is Catholic. The Xavier's CoP is dedicated to bringing minority youth into the learned profession of pharmacy. For years, Xavier has been among the top three producers in the nation of African Americans with a PharmD degree. The CoP's mission is to prepare pharmacists to have an impact on medically underserved communities, particularly African American, to eliminate health disparities through patient-centered care, community service, and scholarly work.

CoP, college of pharmacy; **HBCU,** historically Black college/university; **PharmD,** doctor of pharmacy; **STEM,** science, technology, engineering, and mathematics.

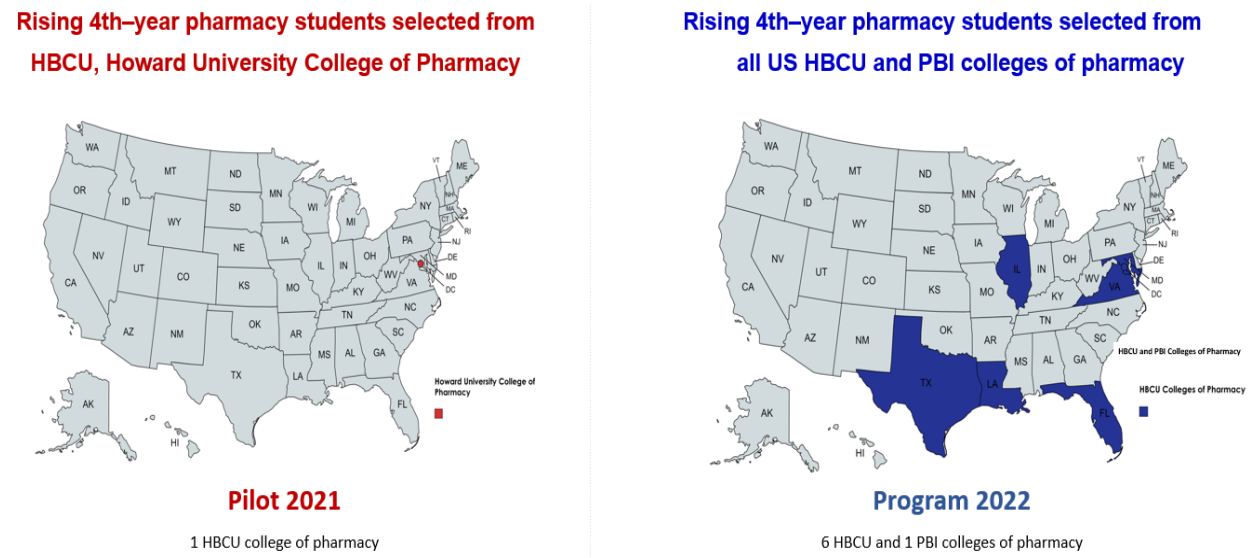
Pfizer GRA program administrators and members of the Pfizer Talent Acquisition, Recruiting and Onboarding Delivery Team hosted a collaborative, cross-institution, kick-off meeting with CoP experiential program administrators and school deans to gauge their interest in partnering with Pfizer GRA to support student participation in the program. In addition, this discussion led to understanding of the individual institution programming practices/operating procedures to create targeted and valuable industry experiences for the students. The following potential program hurdles were identified:

- Requirements for the cross-departmental review process and timelines aligned with the finalization of the education affiliation agreement,
- Preceptor requirements,
- Use of the core experiential-learning management system software to manage student evaluations, and
- Varying block schedule start/end dates across each institution.

Solutions agreeable to both Pfizer and each CoP were identified to overcome these concerns.

All seven identified CoPs expressed interest in partnering with Pfizer GRA, and the program's prospective student pool was expanded to include applicants from each school (**Figure 2**).

Figure 2. Expansion of Pfizer GRA-HBCU-PBI Advanced Pharmacy Practice Experience Pilot Program



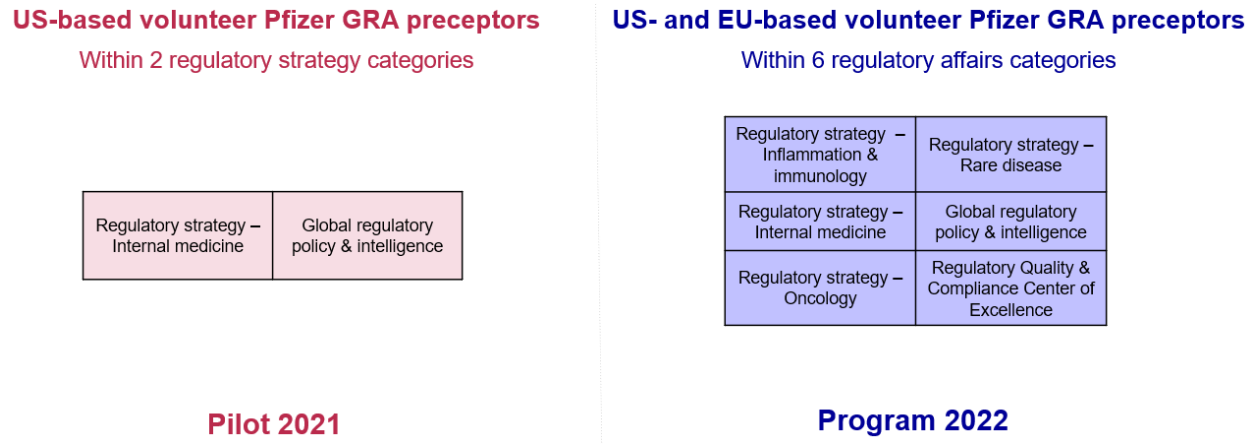
GRA, Global Regulatory Affairs; **HBCU,** historically Black college/university; **PBI,** predominantly Black institution.

Source: Pfizer

In addition, Pfizer GRA program administrators attended virtual preceptorship fairs to further understand the administrative processes and timelines for individual university experiential-learning opportunities. These fairs also served as platforms for interfacing with potential student applicants and providing details of the overall program objectives, selection criteria, and timelines. During the fairs, students were most interested in gaining further information about regulatory science as a profession, connecting with Pfizer presenters to gain a better understanding of a day in the life of a Pfizer regulatory colleague, and discussing the overall skills and experiences that would be instrumental in supporting their candidacy.

Efforts to recruit additional Pfizer GRA preceptors were also prioritized and deemed as important as collaboration with CoP administrators and interfacing with potential students. A small kick-off meeting was initially held with pilot preceptors to confirm participation for the expanded program. Each pilot program preceptor agreed to participate and was retained. Subsequently, pilot preceptors served as program ambassadors and led recruitment interactions with potential new preceptors (**Figure 3,** p. 7). Further awareness about the program was provided via broad advertisement across different internal media platforms (e.g., Yammer, Microsoft Teams, email), commentary provided by senior level leaders during townhalls and podcasts, discussions led by Pfizer CRGs, presentation roadshows hosted within GRA category meetings, and postings included on the GRA volunteer matching portal.

Figure 3. Expansion of Pfizer GRA-HBCU-PBI Advanced Pharmacy Practice Experience Preceptorship Program



Source: Pfizer

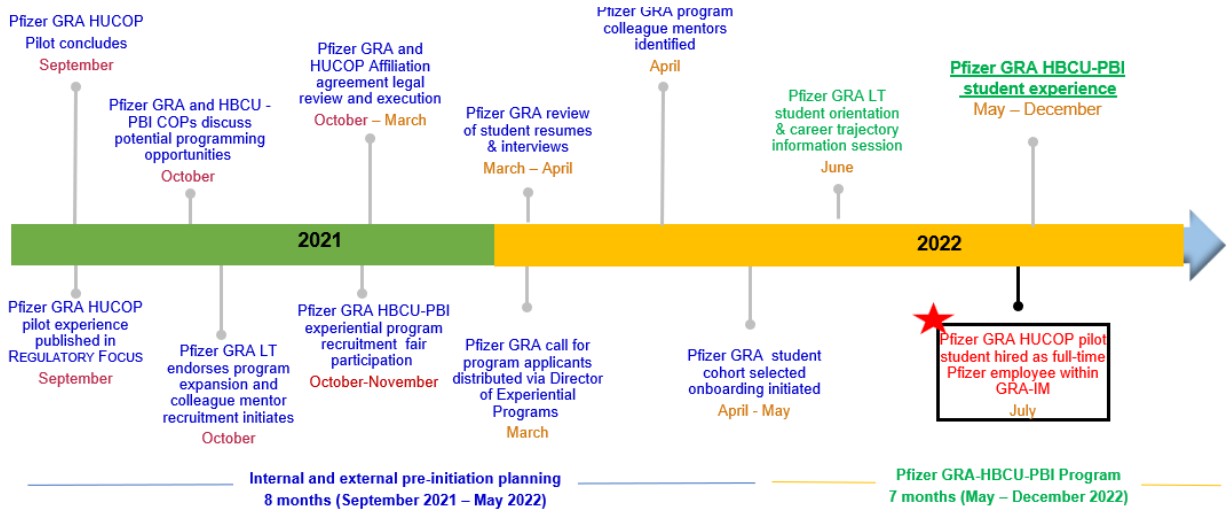
Execution of expanded program

Many of the learnings from the pilot contributed positively to the design of the expanded program. One example of this included maintaining the remote/virtual format to support student access. In addition, the Pfizer-CoP education affiliation agreements/contracts finalization process, which was identified as the key challenge and a rate-limiting activity for pilot program initiation, was optimized. This included extending the overall duration of the contracts/agreements and discussing intricacies and efficiencies early on during the kick-off meeting with the CoPs and Pfizer Human Resources Talent Acquisition. As a result, the agreement duration was extended from 1 to 5 years. Given this, the process will no longer be an immediate barrier unless there are significant program modifications.

A new element of the program design was incorporation of an option for students to participate throughout their institution's academic year rather than the May-to-June timeframe for the pilot. This was a welcomed efficiency from the perspective of CoP administrators, potential students, and Pfizer GRA student preceptors. It allowed for students across universities to participate, despite differing rotation block schedules.

The key challenge associated with the expanded program was internal Pfizer resources. Although the pilot was expanded to a full program with an increased number of CoPs, students, and preceptors, the size of the Pfizer GRA administration team was not increased. As a result, it was challenging to manage activities and track key strategic imperatives with a small team of volunteers with bandwidth constraints (**Figure 4**).

Figure 4. Development and activities timeline of Pfizer GRA-HBCU-PBI CoP Advanced Pharmacy Practice Experience Preceptorship Program



GRA, global regulatory affairs; **HUCOP,** Howard University College of Pharmacy; **CoP,** college of pharmacy; **HBCU,** historically Black college/university; **LT,** leadership team; **PBI,** predominantly Black institution; **IM,** internal medicine

Source: Pfizer

Student applicants were selected based on the following criteria:

- Good academic standing;
- Demonstrated interest in the biopharmaceutical industry, particularly regulatory science;
- Leadership skills and experiences (e.g., FDA/industry, but not required);
- Strong communication and interpersonal skills; and
- Successful interview with Pfizer GRA program administrators.

For students who were not selected, constructive feedback was provided to the experiential-education program administrators about the students' submission materials and/or interview.

Extensive drug development and regulatory science training

Selected students were mentored by Pfizer colleagues at the director level and above, across four therapeutic areas (immunology and inflammation, internal medicine, oncology, and rare diseases) as well as global regulatory policy and intelligence and the Pfizer Quality and Compliance Center of Excellence. Like the pilot, the program was offered remotely/virtually and consisted of the following:

- Curated drug development training provided through the Pfizer training portal (e.g., FDA Code of Federal Regulation (CFR) related to protection of human subjects (21 CFR 50); institutional review boards (21 CFR 56), investigational new drugs (21 CFR 312); requirements for adequate and well-controlled clinical studies (21 CFR 314.126); regulations for biological products (21 CFR 600).

- Regulatory Affairs 101 Training Academy materials to give students an understanding of "a day in the life of a regulatory professional," with vertical and horizontal matrix working models including other line functional colleagues. This content is delivered live, in a didactic format (recordings made available on-demand), by Pfizer cross-functional colleagues representing regulatory strategy; regulatory advertising and promotion; regulatory operations and labeling; regulatory chemistry, manufacturing, and controls; clinical development; safety; toxicology; commercial; marketing; medical affairs; and health evidence and outcomes research.

- Pfizer GRA Learning Academy materials, delivered through a digital training portal and including modules on core elements of regulatory affairs, an understanding of the importance of health authorities globally, insight into regulatory law, guidelines, and positions from an international and national perspective, key considerations for development of different types of products (e.g., small molecules, biosimilars/genetics), and corresponding clinical trial applications (e.g., new drug application, abbreviated new drug application).

- Hands-on experience in regulatory strategy, regulatory policy and intelligence, and regulatory quality and compliance through an assigned project with clear program deliverables (**Table 2,** p. 10), which included:
    - Integration into Pfizer line-function–specific and broader global cross-functional asset teams,
    - GRA category or therapeutic area team meetings, and
    - Project presentation to broad GRA community at the annual GRA Student Research Day.

- Structured networking and professional development opportunities with fellow undergraduate and graduate students, cross-functional colleagues, and Pfizer CRGs (e.g., Global Black Community, Latino Colleague Research Group, Global Asian Alliance).

Table 2. Examples of Pfizer GRA-HBCU Preceptorship Program student projects

Therapeutic area/category	Project topics
Immunology and inflammation	Asset team data readout assessment and formal FDA end-of-phase 2 meeting strategic planning
Internal medicine	• Case study in development and global expedited program designations for specified disease areas • FDA priority review and accelerated approval: Case study assessment • Assessment and presentation of key review aspects from EMA assessment reports
Oncology	• Assessment of global expedited programs for serious conditions • Clinical outcomes assessments and labeling
Rare disease	RWD-RWE in regulatory decision-making
Global regulatory policy and intelligence	• Analysis of FDA multidisciplinary review documents to identify key elements and methodology that may be predictive for achieving inclusion of patient preference data in FDA-approved labels • Analysis PROs assessed in oncology clinical trials and labeling implications in the US and EU
Compliance center of excellence	Integrations and codevelopment business models: Identifying areas of concern and brainstorming solutions to strengthen the understanding of the end-to-end clinical trial process

FDA, [US] Food and Drug Administration; **EMA,** European Medicines Agency; **EU,** European Union; **PRO,** patient-reported outcome; **RWD,** real-world data, **RWE,** real-world evidence.

Pfizer colleague feedback

Qualitative Pfizer GRA colleague feedback outlined in **Table 3** (p. 11) suggests that student mentorship provided individual contributors the opportunity to showcase leadership capabilities, the space to contribute to transforming society through DEI partnerships, and the chance to make significant impact toward building an inclusive and diverse talent pipeline.

CoP administration feedback

Qualitative CoP administrator feedback suggests the Pfizer GRA collaboration was positive and provided a unique opportunity for talented students. Below are two examples of qualitative administrator feedback.

> From initial contact with the HBCU-Pfizer GRA team to the final on-boarding of the students that began the experience, the Pfizer colleagues provided appropriate guidance and essential support to get the partnership established – seamlessly and timely. All expectations were made clear and thus allowed us to execute them in the spirit of 'one team.' Understanding the magnitude of the opportunity, it was considered a major accomplishment to have three of our top-performing students selected. Each one was a member of the college's Industry Pharmacists Organization,

Table 3. Qualitative Pfizer colleague feedback

'The caliber of the students selected across the different colleges of pharmacy far exceeded the expectations of the Pfizer program administrators and preceptors. The students were proactive, driven, and confident in sharing their perspectives on the healthcare system as a whole, as well as the key regulatory science skills they were interested in gaining. Working with the students was a pleasure and a gift. I look forward to supporting them in any way possible as they graduate and enter into the workforce.'
'The primary goal of this new, expanded GRA program was to build the talent pipeline. This was evident for students, however, the value-add from a Pfizer colleague growth-and-development perspective was greater than anticipated. The design and flexible nature of the program allowed the opportunity for all GRA colleagues across the globe within each facet of regulatory affairs to gain more diverse leadership and management experience through human resources onboarding, project selection, training, and student performance review completion. This value was quickly identified by colleagues and is now also considered a unique opportunity for individual contributors with strong leadership skills and experience to lead within Pfizer GRA despite the line function organizational structure.'
'I'm extremely proud of the success of the GRA Preceptorship Program. After the senseless murder of George Floyd, it hit home because he was my cousin. His wrongful death kicked off meaningful conversations and awareness of racial inequality. I'm paying it forward through this program by giving Black/diverse students the opportunity to be mentored by regulatory professionals to gain industry experience and prepare them for their career after graduation. I was involved with the entire process of the program from cohosting a kick-off meeting with the colleges/universities, interviewing and onboarding the students, and handling numerous administrative tasks. It was a wonderful experience, and I look forward to another year working with my colleagues because we're all passionate about the success of the program for Pfizer and the students. It is an experience I'll always cherish.'
'The GRA program proved valuable in more ways than one. As one of two students in the inaugural 2022 class, which showcased the HBCU-Pfizer GRA program, I have the perspective of student and Pfizer GRA colleague. The integrative perspective gained from the range of experiences provided by the HBCU-GRA preceptorship broadened my knowledge base and experience early- to late-stage regulatory product development. Key mentorship with my direct preceptor, Monique Carter, coupled with the support of leadership, set the stage for success. As a recent addition to the Pfizer GRA team, I can say that I had an astounding experience with the program. I am proud of the larger impact this experience provided both myself and future cohorts.'
'As a proud alumnus of an HBCU, where there is an emphasis on excellence, the GRA program was exceptional. The class of 2022 selected were top-tier students. The professionalism and hard work ethic was displayed from the moment the program began. To understand the background and many hardships students overall face, especially those attending HBCUs, has helped paint a clear picture of why such programs are needed, and why HBCU students are needed. There is a push to be the best of the best when competing against those who are not attending HBCUs. The GRA program has cultivated an environment for students to show up as their best self and allow [them] to apply soft skills, communication, critical thinking, etc., through the curriculum of the program. I reflect on my internships standing alone as one among many others who did not look like me or come from a university with such a rich history. Always keeping in mind that I am not representing me alone but many others who stood before me and those to come. The class of 2022 has carried the torch this year and has set a remarkably high standard. I am proud to be a part of an organization that has a focus to increase diverse talent.'

> served in a leadership role and had industry/research as their career destination. Therefore, we considered them very competitive for the opportunity.
>
> *– Administrator 1*

> The exceptional caliber of the overall quality of the [Pfizer HBCU-] GRA experience was validated not only by the fact that two of the three students' evaluation of the preceptor revealed a 4.5/5 rating [but by one of them also noting]: 'I think the APPE is a surreal opportunity for any student selected.' Furthermore, they both requested to extend their time in the 6-week experience. This requested extension could not be granted because they had to move to their next scheduled APPE block. One student, however, chose to participate in projects after the experience formally ended. Of further note here, when the students were asked why they wanted the extension, each indicated it was to try to strengthen their potential candidacy for a full-time position in the organization. At the time of this writing, the third student had not yet completed her experience.
>
> *– Administrator 2*

Student feedback

Student feedback was captured through a voluntary, anonymous, digital Microsoft Forms Survey upon completion of the program. The survey was composed of single-answer, multiple-choice questions (i.e., respondents have to select one answer from a predetermined list of options) and an open-ended question to gain individualized feedback.

Overall, students rated the program and the level of support provided by their Pfizer preceptors as "excellent," when given the following options: Excellent, Very good, Good, Fair, Poor. They noted that the program experience helped them improve their understanding of/experience in regulatory affairs and professional development. All students reported that they are "extremely interested" in pursuing full time-employment at Pfizer within GRA when given the following: Extremely interested, Somewhat interested, Neutral, Not very interested, Not interested at all. **Table 5** (p. 13) includes examples of student feedback in response to the open-ended question.

Conclusion

Pfizer GRA has established meaningful metrics that support the overall goal of growing and maintaining a diverse regulatory science talent pipeline, including:

- Expansion of the Pfizer GRA program to include students from all HBCU and PBI CoPs across the US,

Table 5. Student open-ended question feedback

'Overall, it was a great experience. I think the quality of the preceptor/mentors, as well as [the administrators] who run the program, is what makes it great. The ability to network with so many people is unmatched. I can't really think of anything specifically that could be done better but maybe more networking with other students in other programs could be beneficial.'
'Best [aspects of] the program: • GRA Regulatory 101 Academy – being able to listen in, take notes, and ask questions during live sessions was extremely helpful in increasing my knowledge of the many positions within [regulatory affairs]; • Having weekly 'touch base' with [program administrators]; • Freedom to network within the Pfizer system; • Moments of joy within meetings – it was not just a place of work but a place for sharing and growing with each other; • Diversity/culture – everyone was very welcoming and open to questions; and • Having another [program] student to connect with. *Improvements:* • Having projects prepared and discussed before the student arrives so they can get straight to work on day 1; and • Have students within other departments connect and meet. It [would] allow for a climate check if a student feels they may be doing too little or need additional resources.'

- Global expansion of the program to include recent PharmD graduates based in countries other than the US (i.e., Kenya, Nigeria, Hong Kong), and
- Hiring a Pfizer GRA- HUCOP pilot program student after graduation as a full-time employee within Pfizer GRA as a regional regulatory strategist.

Converting the Pfizer GRA preceptorship pilot experience into an established program has provided the opportunity for a considerable number of exceptionally talented, yet underrepresented, HBCU and PBI future pharmacists to gain invaluable experience toward pursuing careers in pharmaceutical regulatory science.

Acronyms and abbreviations

APPE, advanced pharmacy practice experience; **CoP,** college of pharmacy; **CRG,** colleague resource group; **DEI,** diversity, equity, and inclusion; **EMA,** European Medicines Agency; **EU,** European Union; **FDA,** [US] Food and Drug Administration; **GBC,** global Black community; **GRA,** global regulatory affairs; **HBCU,** historically Black college/university; **HUCOP,** Howard University College of Pharmacy; **PBI,** predominantly Black institution; **PharmD,** doctor of pharmacy; **PRO,** patient-reported outcome; **RWD,** real-world data, **RWE,** real-world evidence; **UPOC,** underrepresented people of color.

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Additional reading and resources

Pfizer website. Workplace diversity & inclusion. https://www.pfizer.com/people/workplace-diversity