Application Summary

Competition Details

Competition Title:	2021 Curriculum Innovation Award
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Application Information

Submitted By:	Andreas Bommarius
Appplication ID:	5996
Application Title:	Andreas Bommarius & Mark Prausnitz
Date Submitted:	02/28/2021 11:52 PM

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Primary School or Department
Chemical and Biomolecular Engineering

Primary Appointment Title:	Professor

Application Details

Proposal Title
Andreas Bommarius & Mark Prausnitz

Nomination of Drs. Andreas S. Bommarius and Mark R. Prausnitz

CTL Curriculum Innovation Award, 2021

Professor David Sholl
John F. Brock III School Chair
School of Chemical and Biomolecular Engineering
311 Ferst Drive, N.W.
Atlanta, Georgia 30332-0100 U.S.A.

February 24, 2021

Dear CTL Awards Committee:

It is my pleasure to nominate Professors Andy Bommarius and Mark Prausnitz for the 2021 CTL Curriculum Innovation Award. The basis for my nomination is their work to create and develop a pair of novel courses that expand beyond the traditional curriculum.

Andy and Mark developed ChBE/CHEM/BMED 4765/6765 D4: Drug Design, Development, and Delivery, first taught in the Spring of 2005. This course is an interdisciplinary, multi-faceted educational experience for seniors and graduate students from multiple departments in the COS and COE focusing on pharmaceuticals. This annual, Spring-term 72-student class is in high demand, often filling within hours after registration opens. The class spans not only the diversity of technical topics important to the development of pharmaceuticals, but also the economic, legal, ethical and other societal issues that shape the field. Readings range from quantitative exercises on science and engineering fundamentals to articles and essays more common in a social science or humanities class. During the latter half of the course, multi-discipline student teams develop case studies on the design, manufacturing, formulation, or delivery of a pharmaceutical in the form of peptides, proteins, gene therapy, or vaccines.

In an effort to provide a still richer educational experience, Mark and Andy developed a five-day, intensive visit to pharmaceutical industry manufacturing facilities over spring break that is offered as an optional component of the D4 course. This program is extremely popular with students, who have visited Amgen, Eli Lilly, Merck, Medtronic, Pfizer, and other leading pharmaceutical companies. These visits include in-depth tours of pharmaceutical manufacturing operations, lectures given by industry scientists and engineers, and direct interactions between students and company professionals.

In 2012, Andy and Mark built open their earlier success by creating ChBE 6800 Pharmaceutical Development. This is a graduate and postdoc-level course taught in the Summer every 2-3 years to participants from several Atlanta-area based institutions (Emory, Georgia State, Mercer, and of course GT). Interdisciplinary teams are given a drug candidate and, in a compressed two-week, all-day format resembling NATO Advanced Study Institutes, study all aspects of drug development, approval, and marketing, including seeking venture capital funding. In the fourth instalment of this class, the class was last taught in hybrid (mostly in-person) format in early August 2020, to rave reviews by the participants.

These two courses have had a profound impact on the seniors and graduate students who have taken them by creating genuinely interdisciplinary settings in which students learn about topics of genuine

societal need. Our core technical curriculum does not always prepare students fully for the scope of issues that can derail development of complex new products such as pharmaceuticals. It is important to note that the concept of an interdisciplinary, combined senior year-graduate class, with emphasis on an a specific industry segment, can be adapted into many of the disciplines in which GT educates large numbers of students. ChBE has started to operate more such classes, including ChBE 4743/6743/CHEM 4803/8803 Fundamentals and Challenges for a Sustainable Chemical Enterprise. The demonstrated success of the condensed format of ChBE 6800 is also an important example of how enriching interdisciplinary experiences can be developed in formats that are useful for our research-active PhD students.

I want to emphasize that Professors Prausnitz and Bommarius are both highly research active, so they could have chosen to stick to the safer path of well-trodden core courses. Their willingness to develop innovative programs that stretch their skills and prepare our students to be effective technical leaders in pharmaceutical is a great credit to them and a positive example for their colleagues. In my view they are ideal candidates for the 2021 CTL Curriculum Innovation Award.

Sincerely,

David Sholl
John F. Brock III School Chair
School of Chemical & Biomolecular Engineering

Description of the innovation

Our goal is to *teach science and engineering in context*: in context with other fields of science; in context with business, economic, regulatory, and other societal influences; and in context with ethical principles that recognize science and engineering to be a human endeavor. We have addressed these broader objectives specifically by developing a *set of interdisciplinary courses* for advanced undergraduates, graduate students and postdoctoral scholars. These courses – presented in three modules – address the field of pharmaceuticals, which is rooted in biological and physical science, in the context of a complex and fascinating industry that impacts our lives at many levels. While pharmaceuticals are our interest and expertise, we see this approach to education as being applicable to many other disciplines, and seek to provide a pedagogical approach that builds on the fundamental knowledge of science and engineering our students learn in other classes and in the laboratory, and shows how that science can be applied to do things such as saving lives, making money, and expanding opportunities *when placed in context with the pharmaceutical industry and its impacts on society*.

The ***first module*** and lead course, Drug Design, Development, and Delivery ('D4'), started to be taught in 2005. In addition to the content, its interdisciplinary character is ensured by admitting juniors and seniors from various Schools, here BMED, ChBE, and CHEM/BCHM, as well as graduate students from an even broader range of departments. The established course numbers thus are BMED/ChBE/CHEM 4765 and ChBE 6765. Our focus industry is the pharmaceutical industry ('Pharma'); the core topics covered in the D4 course are drug discovery, drug manufacturing, drug formulation, and drug delivery, and the class implementation features intensive team projects that facilitate learning course content, as well as teamwork and communication skills. The science and engineering concepts drawn upon in the D4 class are biochemistry, mass transfer, and kinetics and reactor design. As discussed below, *the lectures, discussions and case studies in the course use these technical concepts to explain their broader impacts on society, and how society influences scientific directions and priorities*. We tell students on the first day that while the core content of the course is scientific, its implementation feels in many ways like a humanities course.

A ***second module***, a voluntary weeklong, in-depth tour of pharmaceutical manufacturing facilities during Spring break was added in 2007. The tour is in Puerto Rico, which is one of the world's premier pharma manufacturing locations, and provides an opportunity for many students to experience a new cultural and physical environment. The group typically visits six Pharma companies on the island, usually including two different manufacturing processes in each company. Products seen range from chemical synthesis of small molecule drugs and biochemical fermentation to produce protein therapeutics to fill-finish operations like tableting, vial filling and packaging. *Seeing the industrial implementation and meeting the people who design and operate these facilities provides an orthogonal perspective to the pharmaceutical science in our lectures that not only provides a fuller understanding of the technologies, but puts them into context with the human, economic and environmental realities* of mass producing drugs on a financially struggling protectorate of the United States where 70% of exports are based on pharmaceuticals. We see the most-amazing, cutting-edge manufacturing facilities run by the world's experts, tour one of the oldest cities and fortresses in the Americas, and kayak through a bay of bioluminescent dinoflagellates under a new moon, but also see manufacturing facilities close down from one year to the next, learn first-hand about the effects of Hurricane Maria and see the juxtaposition of one of the wealthiest industries in the world operating among pockets of rural poverty. This unique module has been recognized with the CETL Co-curricular Innovation Award in 2015.

A ***third module*** has been added in 2012: Pharmaceutical Development ('Pharma Development'), a two-week, all-day intensive short course using problem-based learning for advanced PhD students and postdocs conducting pharmaceutical research and drawn from four Atlanta-area universities to experience the process and complex decisions associated with bringing a pharmaceutical product from scientific discover to the market. The module received its permanent course number last year: ChBE 6800. These young professionals work in fixed five-member teams on one drug target per team throughout the duration of the course. Each day a new aspect of drug development is covered, from late-stage drug discovery to formulation to clinical trials to marketing of a newly approved drug. Each morning, a pharma industry expert lectures on the topic at hand; and each afternoon the groups work together to develop the plan for that aspect of their drug in

development, which is supplemented with a 30 min, one-on-one consultation with the industry expert to address their specific questions and ideas. In this way, we bring together engineers, chemists, bioscientists, pharmaceutical scientists and others from Georgia Tech, Emory, Georgia State and Mercer for cross-fertilization of ideas and enhancement of connections within the Atlanta pharmaceutical research community. *We expose the students to leading industry professionals; have them read, analyze, discuss, estimate and make plans; and forge a drug product development plan that will pass muster with "company leadership"* as a product that meets the needs of patients, health care providers, regulators, payers, shareholders and the many others who have a stake in the pharmaceutical industry.

Problem or student learning issue addressed

Most courses for Science and Engineering majors at Georgia Tech focus on textbook- or laboratory-based learning of quantitative, natural laws-based content that is generally about science and is generally presented in the context of meeting scientific objectives. Such courses are advantageous to teach the scientific method and to introduce scientific rigor into the curriculum, and are appropriately the foundation of a good technical education. The few remaining courses for such majors are in the Humanities and Social Sciences, including extensive reading material and discussion in class and may touch on technical topics (e.g., science fiction literature, internet communications) that are usually outside the students' major.

Our vision, as expressed in the three modules of our pharmaceutical education curriculum, seeks to provide interdisciplinary training not only at the interface of scientific disciplines such as chemistry/biochemistry, chemical engineering and biomedical engineering, but also at their interface with industry practice and societal pressures that influence the pharmaceutical industry. This approach takes a perspective that differs from both typical Science and Engineering courses as well as from typical Humanities and Social Science courses:

- The modules link science and engineering fundamentals with Pharma industry practice and related health industry goals, programs, and projects;
- The modules, all electives, channel the students' interest in Pharma and health care, and provide an interface to test their affinity to specific careers in the field as practiced with real-world influences;
- The modules seek to help students to operate in Pharma and related fields during their careers by teaching students about relevant technical and non-technical problems and projects as well as relevant terminology within the targeted fields;
- The modules all are interaction- rather than readings-based and each contain or are even wholly based on team projects and problem-based learning;
- Each module is designed to have the students synthesize knowledge and input from science, engineering, economics, regulations, and ethical considerations to offer solutions to address demonstrated needs (here disease-related patient need).

Objectives of the innovation

The overarching goal of these courses is to give students insight into the drug development process in the pharmaceutical industry. Without specific training, it is not necessarily obvious how to apply fundamental science and engineering principles to this complex field, as the pharmaceutical industry has its own unique culture based on the critical needs of providing drugs that are both safe and effective. For example, while the development process might often be complex and inefficient, the drug product must be of extremely high purity. During the drug development process, activities must be documented much more extensively than in other industries. In addition to the detailed structure of the pharmaceutically active ingredient itself, the Food and Drug Administration (FDA) requires its manufacturing process to be set even before the completion of clinical trials. There are also the variables introduced by having drug delivery in the hands of the consumer, the need to assure safe and reliable compliance and the economic forces that require financial reward for the very high-risk prospect of developing life-saving drugs and that also require cost-effectiveness in a health care system that is our nation's biggest financial sector after defense. Due to these unique circumstances, there is a

need for this course to address the application of biochemical and engineering principles to this industry in the broader context of societal needs.

The three parts of the pharmaceutical industry covered in the courses are drug design, development, and delivery. Drug design, which is drawn largely from chemistry, involves synthesis of the active ingredient beyond the discovery synthesis. Development involves manufacturing and formulation, which focuses on engineering principles in both industrial chemistry and biotechnology. Multiple disciplines, including biomedical engineering, are often involved in drug delivery, the step in which both the route of administration and drug distribution within the body need to be determined and controlled. One of the goals of the training within the course is to highlight the interdisciplinary connections involved in the pharmaceutical development process and thereby train students to impact the industry by taking an integrated approach that streamlines the drug development process.

These educational experiences focus on actual drugs and the processes and issues surrounding their delivery, whether successful or failed, including continual references to actual drug substances (the active ingredient alone) or drug products (active ingredient and delivery vehicle). The class also is kept interesting and relevant through a few key guest lectures by experts in the field. During the final phase of the class, we examine 6 - 8 case studies to apply the general lessons covered in the first part of the class to specific scenarios in industrial and medical practice. Each case study is analyzed for strengths and weaknesses of current and alternative approaches. This emphasis on real industry examples enables both students and instructors to consider the broader impact of the material and the educational philosophy within healthcare, economics, and other fields.

Existing courses on pharmaceuticals at other universities are typically more narrowly focused, for example, on medicinal chemistry aspects of drug design and discovery or on formulation aspects of drug delivery systems. We are not aware of any other courses that integrate drug design, development and delivery in a single course, and explores their connections in the context of broader societal impacts.

Learning outcomes for the intended audience

The specific objectives of The D4 course are to (i) appreciate critical issues, perform analysis, and make quantitative calculations related to drug design, drug development and drug delivery, (ii) integrate concepts from drug design, development and delivery and appreciate their interdependence, (iii) understand the different phases of the pharmaceutical process, (iv) appreciate the role of alternative methods and broader implications of the pharmaceutical process and (v) communicate with professionals in the pharmaceutical community. The Pharma Development course further adds the objectives of (vi) taking a druggable lead compound and developing a plan to bring the drug lead to market (vii) collaborating within an interdisciplinary team to work through the stages of drug development and (viii) explaining and defending the drug development business plan in front of a simulated panel of venture capitalists/ upper management.

Approach taken

Drug Design, Development and Delivery (D4) (CHBE 4765 / CHEM 4765 / BMED 4765 / CHBE 67675)

Because student interest is high and the class fills easily, we have chosen to restrict enrollment to a limited number of students from each major department: CHBE, BMED and CHEM/BCHM. We also restrict the class to ~70% undergraduates and ~30% graduate students, and currently cap it at 72 students total. In this way, the class can then be divided into 24 interdisciplinary teams of three students each for the case study projects. This structure guarantees that the students will be working and communicating with colleagues of other disciplines, just as they would in industry. The class is highly interactive, with interaction and questions not only between students and instructors but, especially during the project team phase, among the students themselves.

As summarized in **Table 1**, the course begins with an overview of pharmaceutical development that features goals, timelines and constraints that guide the industry. Because of the interdisciplinary nature of the course, we also include optional refresher lectures on biochemistry for engineering students and transport processes

for chemistry students. The only prerequisite for the course is one semester of biochemistry. Next, drug design, development and delivery (i.e., the three Ds) are covered for 2-3 weeks each. Finally, the student-led case studies are developed and presented.

Table 1. Syllabus for Drug Design, Development and Delivery (D4) (CHBE 4765 / CHEM 4765 / BMED 4765 / CHBE 67675), Spring 2020

Lecture #	Date	Topic	Speaker
INTRODUCTION			
Lecture 1	7-Jan	Introduction to drug design, development and delivery	Bommarius/Prausnitz
Lecture 2	9-Jan	Challenges of drug design, development and delivery	Bommarius/Prausnitz
Lecture 3	14-Jan	Successful examples and trends of drug development	Bommarius
Lecture 4	16-Jan	Successful examples of drug delivery	Prausnitz
DRUG DESIGN			
Lecture 5	21-Jan	Principles of drug discovery and drug design	Yomi Oyelere
Lecture 6	23-Jan	Principles of drug discovery and drug design	Yomi Oyelere
Lecture 7	28-Jan	Enzyme inhibition and drug design	Yomi Oyelere
DRUG DEVELOPMENT			
Lecture 8	30-Jan	Pharmaceutical manufacturing and formulation:	Bommarius
Lecture 9	4-Feb	Manufacturing of small-molecule drugs	Bommarius
Lecture 10	6-Feb	Manufacturing of protein therapeutics	Bommarius
Lecture 11	11-Feb	Formulation of pharmaceuticals	Bommarius
Lecture 12	13-Feb	Vaccine Manufacturing	Bommarius
Lecture 13	18-Feb	Designing Biotech & Pharmaceutical Facilities in the Real World	Sarah Lanning, CRB
DRUG DELIVERY			
Lecture 14	20-Feb	Pharmacokinetic modeling: oral delivery	Prausnitz
Lecture 15	25-Feb	Polymeric controlled release systems	Prausnitz
Lecture 16	27-Feb	Transdermal delivery	Prausnitz
Lecture 17	3-Mar	Ocular and other routes of delivery	Prausnitz
Lecture 18	5-Mar	Microneedles: science and commercialization	Prausnitz
GUEST LECTURES			
Lecture 19	10-Mar	FDA Regulation of Pharmaceuticals	Alan Minsk
Lecture 20	12-Mar	Clinical Trials	Eric Felner, Emory
SPRING BREAK	Mar 16-20		
Lecture 21	26-Mar	Broader Impact of Pharmaceuticals	Bommarius/Prausnitz
CASE STUDIES:			
Case Study 1: Ocular Latanoprost® (glaucoma),			
	31-Mar	Latanoprost synthesis by chemical synthesis	Team 1
	31-Mar	Latanoprost synthesis by novel chemoenzymatic routes	Team 2
	31-Mar	Topical Latanoprost delivery to the eye	Team 3
Case Study 2: Contraceptive Hormone Patch, Ortho Evra® patch (birth control)			
	2-Apr	Compact synthesis of APIs of contraceptive hormones	Team 4
	2-Apr	Transdermal patch delivery of contraceptive hormones	Team 5
	2-Apr	Other methods of contraceptive hormone delivery	Team 6
Case Study 3: Leuprolide® Implant (prostate cancer),			
	7-Apr	Solid-state synthesis of leuprolide	Team 7
	7-Apr	Enzymatic synthesis of leuprolide	Team 8
	7-Apr	Polymeric controlled release of leuprolide	Team 9
Case Study 4: Trastuzumab® Monoclonal Antibody (breast cancer)			
	9-Apr	Bioproduction of trastuzumab	Team 10
	9-Apr	Antibody-drug conjugate system	Team 11
	9-Apr	Administration routes of trastuzumab	Team 12
Case Study 5: Pulmonary Insulin, Exubra® (diabetes)			
	14-Apr	Production of insulin in yeast	Team 13
	14-Apr	Production of insulin in E. coli	Team 14
	14-Apr	Pulmonary delivery of insulin	Team 15
	14-Apr	Closed-loop and responsive delivery of insulin	Team 16
Case Study 6: Adenoviral Gene Therapy, Luxturna® (gene therapy against blindness),			
	16-Apr	Cell-based manufacturing of vaccines or gene therapies	Team 17
	16-Apr	Viral gene therapy	Team 18
	16-Apr	Non-viral gene therapy	Team 19
Lecture 22	21-Apr	Pharmaceutical Marketing	Charlie Thompson

The Three Ds. During the *overview section* of the course, the instructors describe the integrated process of drug development from discovering the active ingredient to its formulation into a dosage form, its manufacture using suitable reaction pathways, its assessment in clinical trials, the FDA approval process and its introduction into the market, all subject to technical and non-technical influences. One lecture tells the story of three innovators in the drug delivery field and presents innovative drug delivery systems in the context of the technical and human factors that influenced their development and ultimate impact on medicine. Another lecture deals with the development process and business context of the pharmaceutical industry and portrays the risks in developing novel pharmaceuticals.

The *drug design section* presents key ideas behind the search for a compound testable in the clinic and thus to be manufactured on large scale. The *drug development section* lays out the challenges of drug manufacturing and formulation, including small molecules, therapeutic proteins, and vaccines. Foci for each, respectively, are the design of environmentally benign processes to decrease both costs and ecological footprint for small molecules, the complex downstream processing to a pure, virus-free therapeutic protein, and the comparison of eggs and cell culture for the manufacture of drug substance for vaccines. The *drug delivery section* includes lectures on pharmacokinetics, oral tablet and capsule manufacturing, and controlled release, transdermal, ocular and other routes of drug delivery. The final lecture addresses the challenges of bringing a product forward from the initial idea stage through clinical introduction in the context of microneedle patches developed at Georgia Tech

Products covered in *case studies* in the class have included drugs for a range of indications, such as cancer, reproduction, ocular disease, heart disease, and diabetes. Each year the course includes 6 - 8 case studies, and every case study investigates at least two of the three Ds. Each case study is analyzed by a team typically of two undergraduates and one graduate student from at least two but typically three different disciplines. The scope of the case study assigned to each group is intentionally broad so that the students will do their own research, on the basis on a few lead publications provided by the instructors, and develop their own analysis. One week before the project is due, each team meets with one of the instructors to outline the presentation, make their case, and receive feedback. When the group presents its case study to the class, total contact time is 25 minutes per team, with 15 minutes of presentation involving all three team members, followed by 10 minutes of Q&A primarily by the students.

Case Study Example: Ortho-Evra® patch (Johnson & Johnson). One case study focuses on the Ortho-Evra® contraceptive patch, which provides an opportunity to evaluate competing methods of drug synthesis during the design phase, development issues related to cost-effectiveness and safety, challenges of transdermal delivery and resulting medical issues, and the complex socioeconomic issues surrounding birth control. Introduced in 2001, Ortho-Evra® is a transdermal contraceptive patch manufactured and marketed by Ortho-McNeil-Janssen Pharmaceuticals, a subsidiary of Johnson and Johnson. It contains a progesterone analog, norelgestromin, and an estrogen analog, ethinyl estradiol, that are released continuously during each week that the patch is worn. Initially, Evra® was a great success, taking a significant share of the contraceptives market by providing simple and reliable contraceptive using a once-per-week patch. However, post-marketing clinical studies showed that the total estrogen dose from the Evra® patch was significantly larger than that administered by conventional birth control pills, possibly posing increased cardiovascular risks. These issues led to lawsuits and a huge decline in Evra® sales, which was still marketed with new labeling.

In the student presentations, one of the student teams is charged with evaluating the transdermal patch technology used to make Evra® by considering the nature of the skin barrier, the medical suitability of controlled drug release across skin, and the advantages and disadvantages of different patch designs from a technical and human factors standpoint. Another team takes on alternative methods of contraceptive hormone delivery, including oral tablets, subcutaneous implants, intrauterine devices, and other approaches. Hormone synthesis is considered as well: for both ethinyl estradiol and norelgestromin, the conventional methods are chemical synthesis starting from residual materials from plants, such as sitosterol, stigmasterol, and phytosterol from soybeans or tall oil, the latter itself a residue from pulping. The potentially disruptive technology is a biotechnological synthesis route combining fermentation and enzymatic steps, possibly combined with a few purely chemical steps.

In addition to the many interesting technical issues associated this case study, there is a rich set of business, medical, social and political issues as well. For example, the business decision to continue marketing the product with updated labeling, rather than reformulating the patch to administer the intended estrogen dose, is addressed. The ethical implications of this decision are also discussed, along with the broader issue of access to contraception and associated disparities around the world.

Pharmaceutical Industry Plant Tour

During spring break of the D4 course, we offer an optional five-day trip to visit pharmaceutical industry plants in Puerto Rico, which is one of the largest worldwide sites for pharmaceutical manufacturing (**Figure 1**). During the trip, students tour manufacturing facilities and packaging plants to see at least 10 different pharmaceutical and biotechnology manufacturing processes. Groups have visited Amgen, Eli Lilly, Johnson & Johnson, Merck, Pfizer, Wyeth and others, and saw small-molecule drug synthesis, protein fermentation and purification, drug formulation, sterile operations, and product packaging. As the first university group from the main-land United States to visit most of these facilities, our students are greeted by top management and escorted by the plant designers and operators manufacturing insulin, birth control pills and patches, antibiotics, antidepressants, and cholesterol-reducing drugs. The tour ends with a visit to Bacardi, which features a technical tour of the fermentation and distillation processes at the world's largest rum distillery. In their free time, students also kayak through a bioluminescent bay, become familiar with Old San Juan, and broadly experience a cultural environment different from the US mainland.

Figure 1. The Pfizer manufacturing facility in Puerto Rico, where students take an up-front look at how drugs are made at state-of-the-art facilities.

Pharmaceutical Development (CHBE 6800)

The approach taken in the third module – Pharmaceutical Development (CHBE 6800) – divides participants into five-member groups, with distributed specialties, such as biochemistry, chemical engineering, pharmacy, and bioinformatics (**Figure 2**). Each team is given a drug candidate, typically in early clinical trials, described in a recent article in the *Journal of Medicinal Chemistry*. Note that the success of that drug candidate towards approval and marketing is uncertain, which gives students an open-ended problem with no solution found in the literature. Each day, each group covers a different step in the drug development process (see ChBE 6800 syllabus in **Table 2**) and reports on its progress daily. After a lecture on the topic of the day in the morning, the teams work on the assignment of the day in the afternoon in dedicated rooms with large whiteboards.

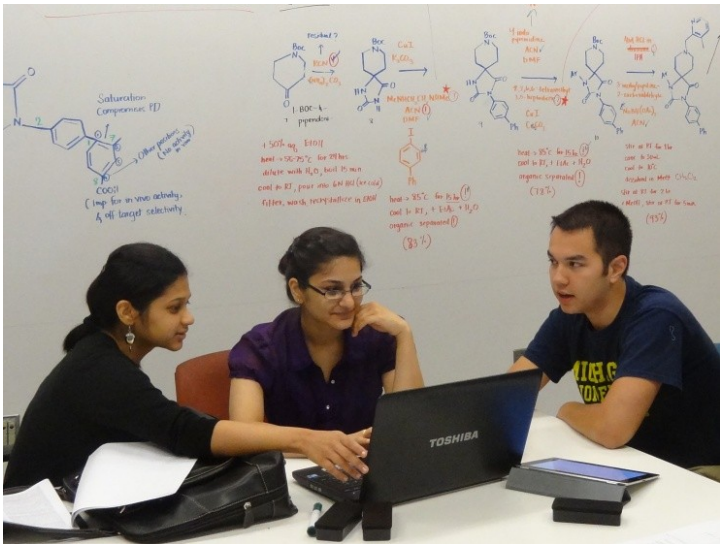

Figure 2. Doctoral students from Mercer and Georgia Tech work together on a drug development plan.

The day's 'expert', typically the morning's lecturer, confers with each team about its approach in late afternoon. On day 9, the groups prepare the final report in form of a slide deck to be presented and defended on day 10 during the final presentation, the 'pitch to upper management' or 'to venture capitalists', respectively.

Table 2. Syllabus for Pharmaceutical Development (CHBE 6800), summer 2020

Class	Topics	Lecturer
August 3	Introduction to class and pharmaceutical development Project teamwork and communication	Bommarius and Prausnitz Mary Lynn Realff, Georgia Tech
August 4	Target indication, commercialization pathway	Viral Kansara, Clearside Biomedical
August 5	From drug lead to drug molecule	Andrew Peat, GSK
August 6	Drug formulation and delivery	Mychael Scoggins, Recro
August 7	Drug manufacturing scale up and GMP	Andy Bommarius
August 10	Regulatory process and design of IND-enabling studies	Alan Smith, 4P Therapeutics
August 11	Clinical trial design	Steven Caras, Arbor Pharmaceuticals
August 12	Pharmaceutical marketing	Charlie Thompson, Axtria
August 13	R&D reports and oral presentations	Michael Natchus, Emory
August 14	Final presentations	Harold Solomon, Georgia Tech Lynne Henkiel, Georgia Tech

Description of how the innovation has been evaluated

The primary source of evaluation is through student assessments through written components such as homework, quizzes, and the final exam, as well as oral presentations and group assignments in the context of the case studies. Performance according to these metrics was varied, with almost all students earning a grade of A or B. Neither instructor is known to be an easy grader, and these strong grades were earned by the students who generally mastered the technical content of the course and were able to put it into broader context.

We also obtained additional feedback from students through surveys. Data from the early offerings of the course – when this feedback was most critical – is shown in **Figure 3**. The results were consistent year-to-year, and indicated strong support for the class by the students, giving scores between 4 and 5 for each of the four questions shown.

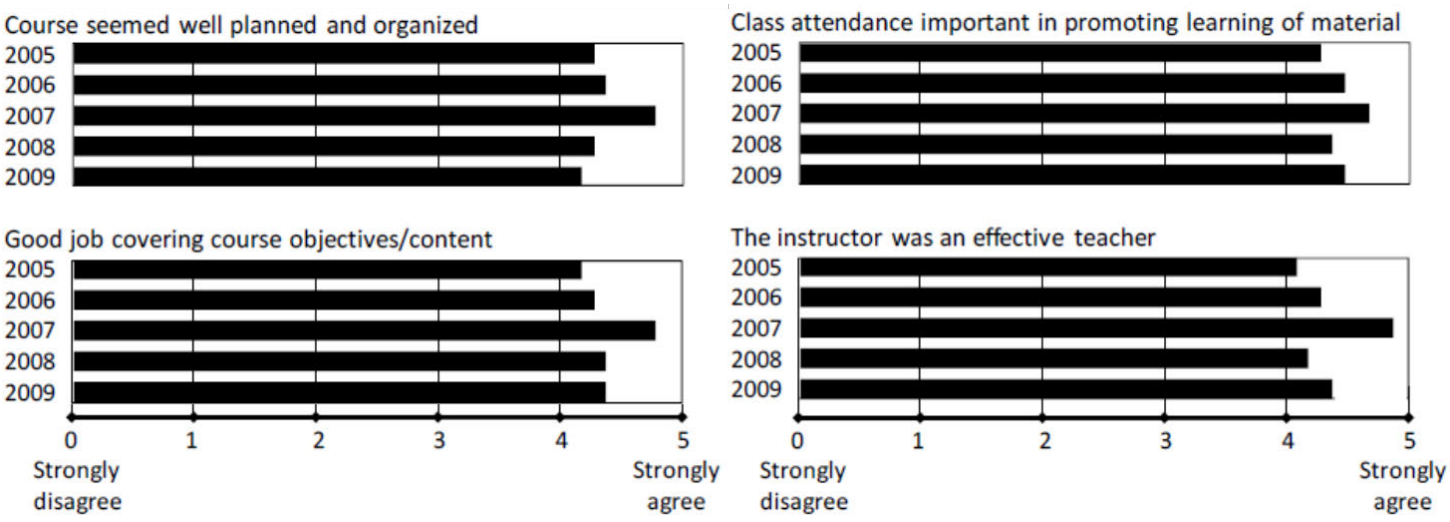

Figure 3. Selected end-of-semester student survey results from the D4 class.

Student testimonials. Reading through the written comments provided by students over the years provides additional evidence that these three educational activities made a large, positive impact on many students (**Table 3**). Students said it was the best course they have taken, that they loved the class, that special educational components of the course (i.e., real-world context, case study format, emphasis on broader impacts, team-based learning, problem-based learning, and access to industry professionals) were recognized as offering great value and seen as setting these activities apart from other experiences they have had before.

Table 3. Testimonials for all three modules of the Innovation

Drug Design, Development and Delivery (CHBE 4765 / CHEM 4765 / BMED 4765 / CHBE 6765)

Quality of the course

This is the best course I've ever attended at GT	I LOVED this course and both professors
This is my favorite class I've taken at Gatech	I loved every part of the class.
One of my favorite classes I have taken at GT.	I loved this class. Super interesting.
One of the best courses Georgia Tech has to offer	I loved the material, and the concepts
Definitely, one of my favorite classes at Tech	Loved this class! happy to have gotten to take it!
I would recommend this class to anyone	I've loved every minute of it
Overall stellar quality and incredibly fascinating	I enjoyed attending this class everyday.
There was never a moment of boredom.	I really enjoyed this class!
Interesting, engaging. Strong knowledge base.	I really liked the course! Learned lots and had fun
The breadth and depth of material available in this course, as well as the organization, is unlike any other class I've heard of at Tech.	
This class is what I thought chemical engineering was when I put that on my application to college	

Quality of the instructors

Two fabulous, caring, and highly effective professors	I have learned so much from Dr. Prausnitz and Dr. Bommarius
He should get an award for outstanding professor	Passionate and very knowledgeable
I always looked forward to his lectures	His teaching still is phenomenal

Value of real-world context

The instructor brought real world applications to the course	It combined the materials learned in many classes with real life industry.
Direct relation to pharma industry, talked about things that are actually in practice	Practical knowledge that could be applied in real world settings
Enjoyed finally seeing some practical applications for the things we learn in ChBE classes.	the class itself did an amazing job of connecting me to the pharma industry

Value of case studies

The case studies used in the course were also extremely excellent and there was great relevance.	Learning about different cases and relating it to the class material was fantastic.
This allowed me to learn even more about the drug design process, then just doing lectures.	The case studies exemplified the broad topics learned in the beginning of the course very well.
That was probably one of the most valuable assignments I've done in my 4 years here.	

Value of broader impacts

This class expanded beyond the classroom	It was an eye opening class.
The debates and class interaction also really helped highlight current and real issues	Teaching the whole picture of the pharma industry and its controversial elements
I've never had so much fun just thinking about ideas that we discuss. I will genuinely miss this course	Morality and ethics are common cross topics in class discussions

Puerto Rico plant trip

The field trip for this class was incredible	The trip to Puerto Rico was exceptional
Being able to go to Puerto Rico with the class is probably the best aspect of this course	I really enjoyed it and the trip to Puerto Rico! Thank you for such a fantastic opportunity!
The trip really facilitated my learning	The trip to Puerto Rico was very enlightening
I learned aspects of the pharma industry that you simply cannot learn in a classroom.	PR trip was amazing to apply the concepts we learned in class to real life manufacturing

Pharmaceutical Development (CHBE 6800)

Quality of the course

Overall excellent course.	Great course!	Really liked it!
I thoroughly enjoyed each day.	It really was a stellar job	Excellent course!
I learned a lot more than I was expecting.	The abundance of knowledge gained in a short period of time	Meticulous organization
I very much enjoyed the layout of the class. It was very different, something that I have not experienced before; it was very refreshing.		

Quality of the instructors

The professors are outstanding	Hats off to Dr. Prausnitz and Dr. Bommarius for conducting the course in the pandemic!
Five-star content lectures	
It's clear that the organizers took lot of time to understand the background and experience of students	

Value of team-based learning

Learnt a lot from my teammates	Good blend of students
The group projects were where I learned the most	Teamwork and interaction with diverse students
Interesting and thought provoking scientific discussions with peers and experts	The best part I liked about the course is working with colleagues from various disciplines.

Value of problem-based learning

Seeing the entire process involved in taking a drug to market
The assignments greatly strengthened the learning process since we got real life experience
Liked the "hands on" aspect of having a particular drug lead that we were going to commercialize and present our plan at the end of the class.

Value of industry lecturers/consultants

High-quality lectures and speakers	Excellent guidance from experts from each topic
The expert consultations and presentations were great.	I thought interaction directly with the "experts" was very well-organized.
Being in academia, it is difficult to get exposed to an industry setting. Being able to meet other professionals in industry in addition to having conversations with them.	
The opportunity to talk to the consultant each day was very unique and allowed us to get our assignment done, but also provided an intimate setting allowing us to ask other industry-related questions.	

CIOS scores for instructors. The following **Table 4** lists the results of the Course Surveys (CIOS) for Item 10: "Considering everything, the instructor was an effective teacher".

Table 4. CIOS question 10 scores for Profs. Bommarius and Prausnitz ('B / P')

Section	ChBE*	CHEM*	BMED*	6765	6800
Year					
2005	4.3 / 4.1	4.3/4.1	3.5 / 4.1	4.3 / 4.1	-
2006	4.3 / 4.3	3.9 / 4.3	3.9 / 4.3	4.0 / 4.3	-
2007	4.3 / 4.5	4.5 / 4.8	4.9 / 5.0	4.1 / 5.0	-
2008	Inc / 4.2	Inc / 4.2	Inc / 4.2	4.2 / 4.2	-
2009	Inc / 4.4	Inc / 4.4	4.1 / 4.4	Inc / 4.4	-
2010	4.5 / 4.3	4.1 / 4.4	4.3 / 4.5	4.3 / 4.7	-
2011	4.0 / 4.7	4.1 / 4.0	4.7 / 4.2	4.5 / 4.7	-
2012	4.0 / 4.2	4.2 / 4.4	4.2 / 4.8	3.8 / 4.0	4.7 / 4.7
2013	4.0 / 4.3	4.5 / 5.0	4.5 / 4.5	4.3 / 4.5	-
2014	4.5 / 4.8	4.5 / 4.2	4.8 / 4.9	4.8 / 4.8	4.6 / 5.0
2015	4.5 / 4.5	4.2 / 4.2	4.5 / 4.5	4.0 / 5.0	-
2016	4.9 / 4.5	4.2 / 3.9	4.5 / 4.3	4.0 / 4.9	-
2017	4.7 / 4.8	4.0 / 4.3	4.5 / 4.5	4.8 / 4.9	4.8 / 4.8
2018	4.6 / 4.6	4.1 / 4.6	5.0 / 4.6	3.2 / 4.6	-
2019	4.9 / 4.7	4.2 / 4.7	4.3 / 4.7	4.6 / 4.7	-
2020	n.a.	n.a.	n.a.	n.a.	4.9 / 4.7
Average[1]	4.4 / 4.5	4.2 / 4.4	4.4 / 4.5	4.2 / 4.6	4.7 / 4.8

' * ': Section 4765: *
n.a.: no CIOS scores during Spring 2020
Inc: no scores, owing to low numbers participating in CIOS (< 10)
1: Average is unweighted mean value among all years

Benefits derived from the innovation

The benefits derived from the innovation are fourfold:

1) Graduates of the D4, Puerto Rico and Pharma Development courses become more knowledgeable professionals with a perspective of the industry in context with economic, societal and ethical concerns;
2) Graduates of the D4, Puerto Rico and Pharma Development courses can make better career choices after exposure to those classes;
3) Courses such as D4, Puerto Rico and Pharma Development improve Georgia Tech's profile with the targeted industry, here Pharma. Such an improvement should lead to increased number of job offers for GT graduates.
4) Courses such as D4, Puerto Rico and Pharma Development improve Georgia Tech's reputation among its peer institutions.

How benefits were measured

We believe that the student Testimonials (**Table 3**) and the support letters shown below provide strong and valuable evidence that the Innovation described in this nomination has made an impact.

As another measure, we note that every large US pharmaceutical company has its preferred list of universities to hire from, often differing by company Division or specialty. That list more often than not consists of just five universities per company (List of Five); the No. 1 department in the field and the leading local University are always on that in that List of Five. Despite most often being neither of the aforementioned, Georgia Tech is now on the List of Five of several large US pharma companies, which was not the case when we started these pharmaceutical education initiatives.

Recent data from 2017-2019 ChBE graduates suggest that about 10% of all BS ChBE graduates find employment in Pharma or attend Medical School (data from Associate Chair for Undergraduate Studies, ChBE). While this appears to represent a significant increase in the number of Georgia Tech BS ChBE graduates being hired by pharmaceutical companies over the years, no quantitative data exist before 2017.

Description of the potential for others to adopt or adapt the innovation

The innovation, in the form of conceiving courses that solidify relevant science and engineering fundamentals while introducing students to an industry or an area of government in context with socioeconomic influences, should be scalable across many, possibly most, Georgia Tech Schools and majors.

- The first module (interdisciplinary senior-graduate student course) requires an *industry or area of government* as a focus; in the current example, this is the *Pharmaceutical Industry*.
- The second module (excursion to co-located agencies of the focus area) requires a *geographic center of activity* for the focus area; in the current example, this is the *Puerto Rico pharmaceutical industry*.
- The third module (time-compressed, all-day short-course for senior graduate students and postdocs) requires a *teachable process* central to the focus area; in the current example, this is *drug development, approval, and marketing*.
- The final ingredient is *instructor(s) with suitable experience* in the industry or governmental sector to teach courses and lead programs that reflect real-world process and broader impacts.

To promote adoption by others, we have disseminated information about these educational advances in a number of ways, including

- Publishing a paper about the D4 course in the leading educational journal in chemical engineering:
    - MR Prausnitz, AS Bommarius (2011) Drug design, development and delivery: an interdisciplinary course on pharmaceuticals, **Chemical Engineering Education**, 45:47-52.
- Publishing news articles featured in Georgia Tech publications and picked up by publications outside Georgia Tech:
    - GT Students Visit Pharmaceutical Plants in Puerto Rico, http://hg.gatech.edu/node/56386
    - Annual trip offers students an intimate view of pharma industry, https://www.bme.gatech.edu/bme/rite-spring-puerto-rico .
- Issuing a press release featured in Georgia Tech publications and picked up by publications outside Georgia Tech about the Pharmaceutical Development course:
    - Atlanta Pharma Community Collaborates on Drug Development Education, https://news.gatech.edu/2012/06/16/atlanta-pharma-community-collaborates-drug-development-education.

Adoption and Adaptation of the innovation by others

Examples for adoption and adaptation

The following serve as examples of adoption and adaptation that can be implemented in other units:

- Industry or area of government: i) Environmental protection for Civil and Environmental Engineering (CEE), Biology (BIOL) or International Affairs (INTA), ii) Transportation for Mechanical Engineering (ME) or Public Policy (PUBP); iii) Semiconductors for Electrical Engineering (EE), Chemistry and Biochemistry, or Computer Science (CS)

- Geographic area of activity: i) Silicon valley, CA for electronics, ii) Seattle, WA for aeronautics, iii) Washington, D.C. for environmental protection, and iv) New York City, NY, for the finance industry.

- Teachable process: i) Environmental impact, ii) Novel car design, ii) iii) New generation semiconductor development.

Scalability across a School (example: ChBE)

The School of ChBE encompasses several intellectual fields, such as Materials, Energy, Biotech, and Process Systems, and is linked to several industries, such as Chemicals, Pharma, or Semiconductors. Significant fractions of ChBE graduates enter these industries. ChBE has several other courses that are compatible with and adapteable to the D4 template. 4743/6743/CHEM 4803/8803 Sustainable Chemical Enterprise (first taught in 2015) already is cross-listed and is being restructured with many elements germane to 4765/6765 D4. Other existing courses, such as 4535 Product Design (first taught in 2004), 4803/8803 Chemical Engineering in Materials Development and Production, or 4813 Energy Systems Capstone could follow.

Resources required to use the innovation

The resources required to adopt (and possibly adapt) the innovation concern i) spending additional teaching units, ii) extra funding, not covered by point i), iii) tapping into a(n) (alumni/a) network for contacts, and iv) ,

Not listed under i) to iv) but crucial to using any module of the innovation is a (likely small) *group of faculty dedicated to its establishment and success*. This resource is *indispensable* but is not listed below.

The first module (interdisciplinary senior-graduate student course) requires a target industry or government activity (here: Pharmaceutical industry) and a list of contributing Schools (here: ChBE, CHEM/BCHM, and BMED). As case study work effectively limits the size of the class (here: 72 students = 8 cases x 3 teams/case x 3 students/team), access needs to be managed well, especially at the undergraduate level and especially across participating Schools. A limited contingent of slots in phase I registration, followed by required attendance and a statement of interest in phase II registration, has worked well for 4765/6765 D4.

The second module (excursion to co-located agencies of the focus area) requires leading institutions acting as hosts for a visit; these hosts might require patience and persistence if they are not used to hosting student groups. The hosts (here: Pharmaceutical companies) effectively set a maximum group size (here: 24 students). Transportation and accommodation require funding, as students should not be expected to pay the full costs for a 4-6 day trip, estimated at $1,000-$1,500/person, unless financial selection of trip attendees occurs. Connection to local experts, even TAs familiar with the locale, greatly helps. An exploratory trip by the faculty members in charge is advised (and was conducted in the case of the Puerto Rico field trip one year in advance).

The third module (time-compressed, all-day course for postdocs and senior graduate students) requires rigorous time management and thus careful bundling of daily activities. Demand should be assessed carefully,

as the pool of eligible potential participants can be much smaller than for the interdisciplinary course (first module). For postdocs and senior graduate students, the summer time often is more conducive for such an all-day course but has to avoid major conferences in the field. A network with world-class experts is required to provide top-notch value to course participants. Group members should have complementary skills.

Georgia Tech Chemical & Biomolecular Engineering

School of Chemical & Biomolecular Engineering
311 Ferst Drive, N.W.
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To: CTL Curriculum Innovation Award Selection Committee
Re: Support letter for Prof. Bommarius and Prausnitz

February 27, 2021

Dear CTL Award Selection Committee members,

It is my pleasure to write this letter in strong support of the nomination of Prof. Andreas (Andy) Bommarius and Prof. Mark Prausnitz for the 2021 CTL Curriculum Innovation Award. Andy and Mark have created three innovative instructional vehicles to integrate real-world situations from Pharma and Healthcare into the education of undergraduate and graduate students at Georgia Tech. Their efforts encompass a broad range of educational activities: an interdisciplinary elective course with extensive student project work, a voluntary weeklong field trip, and a two-week compressed workshop-style course for graduate students and postdocs from multiple local institutions. The initiatives have evolved and been refined over the past decade and have become a highly popular part of the educational opportunities we offer our students. As Associate Chair for Undergraduate Studies in the School of Chemical and Biomolecular Engineering, I have observed the impact of these initiatives first-hand and believe that the efforts are deserving of recognition through the Curriculum Innovation Award.

Andy and Mark jointly conceived and developed the course "Drug Design, Development, and Delivery (D4)", which is now cross-listed between multiple units on campus and co-taught for graduate and undergraduate students: CHBE/CHEM/BMED 4765 and CHBE 6765. At the undergraduate level, cross-listing has been critical for embedding the course into the various degree programs, but the graduate section of D4 (CHBE 6765) also consistently attracts students from multiple Schools and Colleges. D4 is very popular among our student population, and I believe that it has pretty much reached enrollment limits each year since it was first offered in 2005. Routinely, the course is full after Phase I registration, and Mark and Andy have gradually increased the capacity to meet demand, now allowing 72 students between all sections, which is large for this type of elective.

Another instructional vehicle, and a remarkable feature of the D4 course experience (though not the emphasis of this Award nomination), is a voluntary four-day field trip to Puerto Rico, one of the few regions of the world harboring a high density of pharmaceutical production facilities. Participating students tour multiple production plants and hear presentations at leading pharmaceutical companies like Abbvie, Amgen, Eli Lilly, J&J, Medtronic, Merck, and Pfizer. Andy and Mark also ensure that students get exposed to some of Puerto Rico's rich heritage by including a visit to a bioluminescent bay (a very rare natural treasure), a tour of historic sections of San Juan, as well as of the world's largest rum distillery at Bacardi.

The third initiative to be highlighted as part of this nomination is a CHBE 6800 "Pharmaceutical Development" (Pharm Dev). This course, which is a spin-off from D4, was first taught in 2012, then again in 2014, 2017, and, under for the first time under its permanent course number, in 2020. The unique feature of the course is that it is open to graduate students and postdocs from all Atlanta-area universities, and has seen numerous enrollees from

Georgia State University (with its Center for Drug Design), Mercer University (with its School of Pharmacy), and Emory University (with the Emory Institute for Drug Development, Winship Cancer Institute, etc.). To accommodate the needs of graduate students and postdocs from different institutions, Pharm Dev is a highly immersive experience: this for credit course meets all day long for two weeks. Participants are assigned into groups of 3-5 students with different backgrounds and strengths. Each group focuses on the 'development' of one drug or drug candidate, from patient population and lab synthesis to the manufacturing process and FDA approval. Mornings are reserved for short lectures and Q&A, whereas afternoons are reserved for team work on the task of the day. The format mimics the well-known NATO Advanced Study Institutes.

The D4 course (4765/6765) provides an interdisciplinary, multifaceted approach that not only revisits science and engineering basics with regards to drug design and optimization, manufacturing, formulation, and drug delivery, but also introduces industry-relevant aspects and links the process to broader societal issues. While homework assignments and short quizzes help students keep up-to-date with the material, the reading materials often provides a deliberate touch of a social science or humanities class. Other topics, such as clinical trials and FDA approvals, are covered by guest lecturers. After covering the basics, students take over and present case studies on design optimization, manufacturing, formulation, and delivery of actual drugs. The case studies cover different disease areas; examples from recent years are glaucoma, high blood pressure, birth control, fertility, prostate and breast cancer, depression, gene-based loss of vision, and influenza. The pharmaceutical products and therapies cover a wide range of options: small molecules, peptides, therapeutic proteins, gene therapy, and vaccines. For Georgia Tech students about to enter the workforce, the course provides valuable insights and options for self-reflection, as it plants the seed that will enable graduates to work effectively in teams with members from a variety of educational and training backgrounds.

Within ChBE, the D4 format of a multidisciplinary, multilevel course linking science and engineering basics with industry applications solving societal challenges has been replicated in other courses, such as "Fundamentals and Challenges of a Sustainable Chemical Enterprise" (CHBE 4743/6743, CHEM 4803/8803). With such senior-level elective courses, our undergraduate and graduate students are exposed to a broad range of topics before graduation, improving engagement and enthusiasm. As Associate Chair for Undergraduate Studies, I can state without reservation that D4 has been an inspiration for the development of other ChBE "breadth electives" that teach students about state-of-art science and technology within the broader context of industrial processes and related societal issues. From my conversations with graduating seniors (in exit interview) and alumni (when they return to campus as recruiters), these types of courses greatly enhance the student educational experience, provide motivation to perform well academically, and assist in their career choices. After spending most of their time at Georgia Tech in foundational courses that are essential for developing technical skills, electives like D4 give students an inspiring view on the post-graduation future, which many students find uplifting.

For me as Associate Chair, a significant challenge each year is to manage enrollment for the coveted seats in D4. The undergraduate sections are routinely oversubscribed, and the instructors and ChBE Advising Team carefully attempt to distribute the opportunities based on degree-related needs and student interests. The success of the course has made it an annually recurring issue during Phase II, but that is a sacrifice we gladly make for this important course offering. Few electives in ChBE are offered every year, but due to strong demand and extremely good student feedback, D4 has been on the schedule every year for more than a decade.

I also played a role in obtaining approval from the Institute Graduate Curriculum Committee for the unique scheduling of CHBE 6800 and worked with the Registrar's Office Scheduling team to get the Summer 2020 on the course schedule. When presenting the proposal for a permanent course number to the IGCC in February 2020, I sensed a high level of enthusiasm among the committee. Several committee members expressed interest in the concept and wondered whether their Schools could offer a course in that immersive format as well.

In summary, I believe that Prof. Andy Bommarius and Prof. Mark Prausnitz are extremely deserving of the CTL Curriculum Innovation Award. They never let institute procedures and past practices get into the way of their vision on how to effectively educate our students. Over the years, they have devoted a great deal of thought, time, and energy into making these courses a rewarding experience for their students. The instructional vehicles they have developed for Pharma and Healthcare education involve students, faculty, scientists, and engineers from many different academic units on and beyond the Georgia Tech campus, and help to prepare future leaders in multiple sectors of the pharmaceutical industry. Georgia Tech is indeed fortunate to have this type of educational experience to offer its students.

Sincerely,

Victor Breedveld
Professor and Associate Chair for Undergraduate Studies
School of Chemical & Biomolecular Engineering
breedveld@gatech.edu

23-Feb-2021

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Dear Award Selection Committee:

I am delighted to write a support letter for the nomination of Andreas Bommarius and Mark Prausnitz for the 2021 Curriculum Innovation Award. Since my PhD at Georgia Tech in Chemical and Biomolecular Engineering in 2008, I have worked for MSD (known in the USA as Merck & Co., Inc.) for the last 12 years and I am currently Director of the Pharmaceutical Technical Operations department at MSD's Manufacturing Division in Singapore. I took the course 6765 (then still 8803) D4: Drug Design, Development, and Delivery (often just termed D4) in 2004, during its year of inception and acted as one of its teacher's assistant (TA) in 2006 and 2007 on the Puerto Rico field trip to visit Pharmaceutical plants. To this day, the D4 course remains one of my most memorable courses at Georgia Tech, if not the most memorable one. After taking the necessary core courses for the PhD, which of course were rigorous but often narrowly focused on engineering, the D4 course was different: a class with colleagues from different majors, ChBE, CHEM, BMED, and others, both seniors and grad students, teaching the basics of drug design, drug manufacturing, and drug delivery, building on rigorous first principles, but dealing with actual drugs, patented and generics, small molecules, peptides, therapeutic proteins, and vaccines. The course did not just require science and engineering knowledge but through the variety of reading assignments familiarized the students with the pharma industry, drug development, and regulatory affairs, such as drug approvals, and with the societal consequences of the pharma industry, such as drug pricing, the opioid crisis, and pharmaceutical coverage in less-resource-rich countries.

The group projects were another highlight of the course. Groups of three students, selected to represent different majors, as well as graduate and undergraduate students, were given a drug and the task to research a particular aspect of structure optimization, manufacturing, formulation, or delivery of the drug. The drugs covered various ailments, ranging from glaucoma, birth control, high blood pressure, prostate cancer, diabetes, to influenza, and nowadays depression, cancer, and even gene therapy for restauration of vision. Oral presentations, with detailed feedback from both Drs. Bommarius and Prausnitz on the same day of the presentation and written reports (a week later) enabled an in-depth perspective of the task at hand.

The Pharmaceutical Marketing lecture, the last one of the semester, always was a real highlight. The students were astounded how many forces move the market of pharmaceuticals, from government to insurers, to hospitals, to family doctors.

The techniques and the skills we learned, and the perspective we gained, was invaluable for our future careers. I believe having this insight gave me a unique perspective over peers when applying for jobs. I was able to have firsthand experience of the diverse technologies used in manufacturing and set the bar on what teaching innovation should look like. The unique convergence of classroom work, project, plant tours and business allowed to get an unparalleled enterprise, end-to-end view of the pharmaceutical industry.

The annual field trip to Puerto Rico, my home, was a key element of the experience. It allowed me to not only see first hand the different manufacturing technologies but also gave me the opportunity to develop a professional, long-lasting network that to this day continues to bear fruits (e.g., cross collaboration with colleagues at Amgen, Pfizer, MSD, GSK, among others that I first met during the plant tours).
Drs. Bommarius and Prausnitz deserve an award for starting and developing such an impactful class and field trip. Georgia Tech's reputation is vastly enhanced by unique experiences such as the D4 course and its further developments.

Signature
Sincerely,

Eduardo Vázquez Figueroa, PhD, PE, PMP
Pharmaceutical Technical Operations Director

To: CTL Award Selection Committee

Hello,

My name is Amir Hejri and I am a graduate student of School of Chemical & Biomolecular Engineering. I am writing this letter in support of the course package nominated by Prof. Andy Bommarius and Prof. Mark Prausnitz for the Curriculum Innovation award. I have been part of this curriculum for the past four years either as a student or TA. I took both D4 and Pharmaceutical Development classes, and served as the D4 class TA for three consecutive years. This has been, undoubtedly, one of the high points of my grad school experience at Georgia Tech so far. In the following paragraphs, I highlight how some of the most innovative aspects of this curriculum influenced my professional development and other students in class.

First and foremost, the course is structured so that the learning experience is not only limited to the lectures, and the instructors are not the only ones who contribute to the learning. It is an intellectual journey that both students and instructors are taking together where every single person in class contributes to the learning experiences**.** This is especially reflected in the second half of the semester when every class features a group of students presenting their case studies and essentially becoming the instructor for the day. They become the expert in that topic which leads to a tremendous amount of communication between students as other students would go to them to ask questions and learn more about their topic. As the class TA and student, I witnessed a level of student engagement and communication that was far greater than any other class that I had taken before. This decentralized teaching strategy is a unique and innovative approach to increasing students' engagement in learning which is certainly a flagship feature of the D4 class.

What also contributed to the high level of student engagement/motivation in class was the fact that the instructors were able to effectively spark the curiosity in students in the beginning of the semester. The first few classes would concentrate on laying out an overview of what will be taught throughout the semester and explaining why those topics matter and how they can help to solve real-world problems. Early on, the instructors built and presented learning experiences around deep questions and the current global problems, what inspired and fascinated them about this topic in the first place, paid attention to what fascinates the students today, and worked to convey the significance of the contents of the course. In fact, they would take any opportunity to remind students of the importance of their learning; for instance, when an expert from a prominent pharma company was going to give a talk at Georgia Tech on a topic that related to the course materials, the instructors would distribute the flyers to the class through Canvas announcements and encourage students to attend the talk. I saw many of our students attending those talks and asking intelligent questions from the speaker based on what they had learned in class. Students would often express to me how much D4 has helped them in their professional development, to boost their confidence when starting a conversation with an industry expert, and that they were able to stand out in job/internship interviews using the knowledge they acquired in class. One graduate student mentioned that he was able to answer most of his job interview questions only based on learnings from D4 class and he was offered the job at Merck.

The instructors used multiple means of representations in teaching that included writing on the board, showing PowerPoint slides, playing videos, and other visual aids. Each lecture was often a combination of two or three of these methods which reduced the monotonicity associated with teaching only in one format (say, writing on the board) that could translate to students' disengagement and boredom during lectures. In addition, each method, when used appropriately, can facilitate learning; for instance, some of the videos and visual aids used in lectures really helped me gain a better understanding of the topic that otherwise would have been difficult to convey via verbal explanations or writings, and vice versa.

In the past there have been times when I felt lost, sometimes in the middle of the semester, since I was not able to identify how what I am learning today relates to what I learned a month ago or in the beginning of the semester. Every lecture somehow seemed disconnected from the previous ones and that really hampered my learning. The syllabus for this course, however, is uniquely designed to divide the course materials into big chunks of knowledge. I could refer to the syllabus anytime during the semester as a guide to organize information and understand how each section, like a puzzle piece, fits into the previous or next section to form the big picture. As such, instead of forming sparse bits of knowledge, I was able to create an interconnected knowledge map which significantly improved my learning experience and critical thinking power. Besides the syllabus, all the other aspects of the class including learning objectives, expectations, gradings, assignments, report, etc. were also clearly defined and explicitly communicated with the students.

The professors insisted on grading and returning the quizzes as soon as possible (within 7 days) so students can get feedback on their performance faster. Many students indicated in their course survey that they appreciated the fast returning of the quizzes as it reduced their stress levels and provided rapid feedbacks. Dr. Bommarius and Dr. Prausnitz would always be looking for ways to improve the learning experience for students. They would carefully examine students' CIOS course survey at the end of semester. They would also ask for my insights from interacting with students as the class TA to identify ways to enhance the quality of teaching and learning.

The professors both have very relatable and charismatic personalities. They used humor, personal disclosure, and a description of their own intellectual journey to create a sense of community in the class. They always made themselves available and would often stay after class to chat with students. This further nourished students' experience via building a safe and positive environment for learning to occur. This sense of community usually stuck with students even after they graduated – one student who took D4 and then went on to work in a Biotech company after graduation, later on returned to give a lecture in class about her work in industry and how D4 helped her succeed in her career.

After taking the D4 class and then serving as the class TA, I also took the Pharmaceutical Development class last summer. This was a one-of-a-kind course unlike any other course I have taken or heard of before. It brought many experts from different institutions across the metro Atlanta together in the form of Atlanta Pharmaceutical Development community. It was an incredible networking opportunity as well as a priceless learning experience. I found it extremely helpful that professors emphasized on the importance of working in interdisciplinary teams which accurately describes the dynamics of teamworking in Pharma industry. They dedicated the first day of the class to a personality test activity called Clifton Strength assessment that focused on effective teamwork through recognizing each other's strength. My teammates and I found that activity very useful as we worked together for the next 12 days on our project as a team.

My involvement in this curriculum in the past four years has significantly shaped my intellectual development and has created so many new opportunities for my future career. Dr. Bommarius and Dr. Prausnitz have created a well-structured outstanding model for modern teaching and learning in higher education that can be adopted in other courses as well. I strongly support this nomination for the Curriculum Innovation award.

Please feel free to contact me if you have any further questions.

Best,

Amir Hejri

Amir Hejri

To: The CTL Awards Selection Committee 24 February 2021

Subject: Curriculum Innovation Award 2021

Dear Committee,

It is an honor write a letter supporting Dr. Bommarius and Dr. Prausnitz in appreciation of their tremendous work in designing and executing the interdisciplinary drug design, development, and discovery (D4) course. The combined elements of this course are directly in line with the high value, high impact education that Georgia Tech is known for providing. When I think back on my combined ten years of higher education, this course continues to stick out in my mind for its utility, uniqueness, and overall impact on my professional development. Therefore, I fully endorse their nominations for this award.

In modern times, I doubt there has ever been as much scrutiny or regulations placed on the pharmaceutical industry complex as have been during the ongoing global pandemic. As such, experienced and innovative professors are crucial to educating future scientists and engineers on the realities and complexities of what they will face if they choose to enter this field of work. Seven years after taking this course, I am now one of those scientists. I continue to use the lessons learned and perspectives shared during this course to execute solutions for my pharma clients on a regular basis. I believe there can be no higher indicator of the success and impact of a single class than on the ability to still apply the knowledge years later.

In addition to engaging content, stepping outside the classroom is a proven method of instilling a deeper level of understanding as well as inspiring more curiosity about a field. The D4 course contains a particularly unique component consisting of a trip to a large hub of pharmaceutical industry in Puerto Rico. Even more valuable than the content of the class was the ability to visit, observe, and interact with the entire process of drug development and manufacturing direct from some of the largest global pharmaceutical companies. The additional culture experiences during the trip also served to broaden our perspectives and remind us that our goals are to improve the human condition, not just our own.

On a more personal level, the design of the course allowed for students to participate fully no matter their financial ability. The cost of the Puerto Rico trip was significantly supplemented which removed the financial barrier that can prevent students from accessing this level of professional insight and exposure. I am proud that Dr. Bommarius and Dr. Prausnitz were ahead of the more recent trend of ensuring higher education and top opportunities are not solely accessible to those who can afford it. Innovative design is accessible design.

A cornerstone of a Georgia Tech education is the ability to tackle real-world challenges in new and innovative ways. The D4 course not only represents this idea, but specifically prepares students for doing exactly this in their future professions by providing a holistic and realistic education of the pharmaceutical industry. I am one of the many students who has benefited from the work of Dr. Bommarius and Dr. Prasnitz in conceptualizing and implementing such a fantastic educational and practical experience. Both professors are more than deserving of recognition for their significant contributions to innovative learning techniques and accessible professional opportunities.

Sincerely,

Ashley Zuniga, PhD
Global Project Manager, Emerging BioPharma
IQVIA
GT BCHEM 2014

February 27, 2021

Charlene Rincón, Ph.D.
Director Manufacturing
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One Amgen Center Dr.
Thousand Oaks, CA 91320

Dear CTL Awards Selection Committee,

I am writing to recommend Dr. Mark Prausnitz and Dr. Andy Bommarius for the 2021 Curriculum Innovation Award. I had the opportunity to plan and coordinate with Dr. Prausnitz and Dr. Bommarius the Drug Design Development and Delivery field trips in 2007 and 2008. Their efforts to make this field trip a reality started in 2006 with planning meetings and a scouting trip to Puerto Rico to establish the different contacts in the biotech and pharmaceutical companies they wanted the students to visit as part of the trip. They wanted to provide the students with a unique and innovative way to see the concepts taught in ChBE 4765 applied to real biotech/pharmaceutical processes and an opportunity to integrate their learnings from the field trip with the course curriculum. It was with tremendous enthusiasm and dedication that the professors built a creative way of teaching the students, through interdisciplinary and multi-angle courses with an outside the classroom learning experience, to learn the current processes and challenges of the biotech and pharmaceutical industries. The students participating in the trip had to prepare a short presentation of the companies they were going to visit. This requirement provided the students participating in the trip and those who didn't an opportunity to learn more and increase their interest in the processes and companies that were part of the field trip. The field trip not only exposed the students to real life demonstrations of what they learned in the classroom but also provided them exposure to potential future employers.

As a hiring manager in one of the largest biotechnology companies I see the real value of interdisciplinary, multi-angle courses, that give students the opportunity to learn about real-life manufacturing processes while in undergraduate and graduate school. I am certain the learnings from such courses are invaluable to the student's academic and professional career development.

The innovative, high quality, and creative approach to teaching shared by both Dr. Prausnitz and Dr. Bommarius, as well as their effort to expand the horizons of the typical Georgia Tech experience to include a field trip and real-life demonstrations, makes them both excellent candidates for this award. Please feel free to contact me if you have any questions or would like any additional information.

Sincerely,

Charlene Rincón

Dear GT Award Selection Committee,

I write this letter in strong support of the nomination of Professors Andreas Bommarius and Mark Prausnitz for the Curriculum Innovation Award 2021. Their D4 course focusing on pharmaceuticals, and the attached field trip to pharmaceutical plants in Puerto Rico, opened a new perspective for me. It presented me with academic focus on the pharmaceutical industry outside of the standard Chemical Engineering curriculum and gave me real-life exposure to pharmaceutical plants while I was still an undergraduate at Georgia Tech.

It has been over a decade since I took the course in the Spring of 2010. However, it is now as a hiring manager that I see the benefits that the innovative curriculum provided me. Working with and hiring chemical engineers in entry level positions, it is evident that most chemical engineering curriculums are geared towards other industries, and I've found myself having to teach new hires about the drug development process, regulatory phases, and manufacturing nuisances that are unique to the pharmaceutical industry, as part of their onboarding experiences. It is now that I realize how fortunate I was to come into industry with that foundational knowledge already, and why I believe the curriculum is deserving of an innovation award, as it is without a doubt setting engineers at Georgia Tech with an advantage in the field.

On a personal note, I found the trip portion of the curriculum to be fantastic. Outside of the obvious academic benefits of visiting different manufacturing facilities, being able to compare pharmaceutical manufacturing with beverage manufacturing, and visiting the now sadly defunct Arecibo radio telescope, it served like a phenomenal team building activity that resulted in a stronger post-graduation network with peers within the pharmaceutical industry.

Finally, during these pandemic times, when the vaccine design, delivery, and development are more under the microscope than ever, I hope innovative curriculums like D4 are given the opportunity to be positively highlighted and featured in academia as much as possible, and I believe the 2021 Innovation Award provides the right opportunity to do so. I am hopeful that you feel the same.

Sincerely,

Carolina Pérez

Associate Director of Operations

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West Point, PA

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