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The pharmaceutical biotechnology content of pharmacy programs within Europe: A survey

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Abstract
Genetic engineering and allied technologies have underpinned the development of a range of pharmaceutical products of modern biotechnology, collectively termed biopharmaceuticals. Twenty-five percent of all new drugs now approved are biopharmaceuticals and some 140 such products have gained marketing approval. Given the increasing prominence of this class of therapeutic product, it is of interest to survey the pharmaceutical biotechnology content of pharmacy curricula. Commissioned by the European association of pharm biotechnology (EAPB) this 13-question survey focused upon the lecture complement of biochemistry, microbiology and molecular biology, as well as the content of core pharmaceutical biotechnology taught within European undergraduate degree programs. Forty replies were obtained from different pharmacy departments across 15 European countries. The mean numbers of lecture hours delivered in biochemistry, microbiology and molecular biology were 61.8 ± 32.2, 52.4 ± 27.7 and 34 ± 16.4, respectively. For each subject, the number of lectures differed significantly between different institutions, reflected in the large standard deviation observed. Thirty-three of the 40 survey respondents (82.5%) include core or elective courses in pharmaceutical biotechnology. The mean number of lecture hours delivered was 29.9 ± 18.6 h and the courses are mainly taught in third or fourth year. Very significant variation in pharmaceutical biotechnology course content was also observed. Given the now central importance of biotechnology within the pharmaceutical sector, it is perhaps timely to consider these issues in greater detail.

Keywords: *Pharmaceutical biotechnology education, biopharmaceutical curriculum, fermentation technology, monoclonal antibody*

Introduction

A substantial proportion of traditional pharmaceutical products are produced in biological systems. Examples include a range of antibiotics produced by fermentation technology, polyclonal antibody preparations used for purposes of inducing passive immunity and a range of hormones such as insulin extracted directly from mammalian tissue. The development in the 1970s of recombinant DNA technology (genetic engineering) and hybridoma technology marked the birth of the "modern" biotech era (Jackson, Berg, & Symons, 1972; Lobban & Kaiser, 1973; Kohler & Milstein, 1975). Recombinant DNA technology facilitates the large-scale production of virtually any protein in engineered microbial, animal or plant cells (Glick & McMahan, 2003). Hybridoma technology facilitates the convenient large-scale production of a specific protein type, monoclonal antibodies, using transformed hybrid mammalian cells (Shepard, 2000). These technologies facilitated the development and approval for medical use of a range of therapeutic proteins now known as "biopharmaceuticals" or "products of modern biotechnology". By 2003 in the region of 140 biopharmaceuticals had gained marketing approval and some 250 million patients had been administered these products (Walsh, 2003). Some 25% of all new drugs approved since 2000 are biopharmaceuticals and an estimated 371 candidates are currently in clinical trials in the USA alone (PhRMA, 2002). While the vast majority of biopharmaceuticals approved to date are therapeutic proteins,

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the term now also encompasses nucleic acid-based products used for purposes of gene therapy, as well as cell- or tissue-based therapeutic products.

Given the increasing prominence of this class of therapeutic substance, it is of interest to review the pharmaceutical biotechnology content of modern pharmacy degree programs. The survey reported herein was commissioned by the European Association of Pharma Biotechnology (EAPB; www.eapb.org), and aims to determine the pharmaceutical biotechnology content in the curriculum of a representative sample of European pharmacy programs.

Methods: Survey design and execution

The one-page survey questionnaire designed is presented in Appendix 1. It was deliberately limited to a single page in order to maximize the likelihood of completion by respondents who invariably work under significant time pressure. The initial six background questions focus upon the lecture complement of biochemistry, microbiology and molecular biology undertaken by pharmacy students. The remaining questions focused specifically upon pharmaceutical biotechnology. They are designed to determine at what stage within the program pharmaceutical biotechnology is taught, and to what level in terms of lecture duration, laboratory content, syllabus and reading material provided/recommended.

The survey form was distributed electronically to members of the EAPB. By this means, it was delivered to one or more members of approximately 67 pharmacy departments throughout Europe. Data was collected over a 4-month period. Forty replies from different pharmacy departments were obtained, representing a response rate of 59.7%. A good geographical spread was also evident. Responses by country (with the number of different pharmacy programs within that country from which data was obtained listed in brackets) were: Belgium (two), Denmark (one), Finland (two), France (three), Germany (five), Greece (two), Hungary (one), Ireland (two), Italy (five), Poland (five), Portugal (one), Slovenia (two), Spain (two), Turkey (two), UK (five). Although the majority of returned surveys were full and complete, one or more questions within a minority of replies were either unanswered or were answered in an ambiguous fashion. Only full and unambiguous replies were included in the data presented below. The number of usable replies for any given question is provided in the appropriate figure caption.

Results

The initial six survey questions profiled the content of biochemistry, microbiology and molecular biology within the undergraduate pharmacy programs. The results are presented in Figures 1–3. The mean

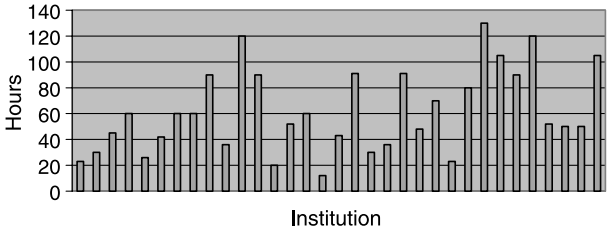

Figure 1. Lecture hours of biochemistry undertaken within pharmacy degree programmes ($n = 33$).

number of lecture hours of biochemistry undertaken was 61.8 h. However, a large standard deviation of ± 32.2 was evident, with the lowest reported lecture load being just 12 lectures while the highest lecture load reported was a very significant 130 h (Figure 1). In all but three cases biochemistry was taught as a stand-alone subject. Biochemistry was taught mainly as a second year subject (14 of the programs). Five programs taught it as a first-year subject while six taught it as a third-year subject. A further five programs taught the subject over two or more years: first and second year (one program), second and third year (two programs), second, third and fourth year (one program), first, second, third and fourth year (one program).

The mean number of lecture hours of microbiology undertaken was 52.4 h. As in the case of biochemistry, a large standard deviation of ± 27.7 was evident, with the lowest reported lecture load being just seven lectures, while the highest lecture load reported was 120 h (Figure 2). In all but five cases microbiology was taught as a stand-alone subject. It was taught mainly as a second- or third-year subject (in nine and seven of the programs, respectively). Three programs taught it as a first-year subject, while one taught it as a fourth year subject. A further eight programs taught the subject over 2 or more years: first and second year (one program), first and third year (one program), second and third year (four programs), first, second, third and fourth year (two programs).

The mean number of lecture hours of molecular biology undertaken was 34 h. Again a large standard

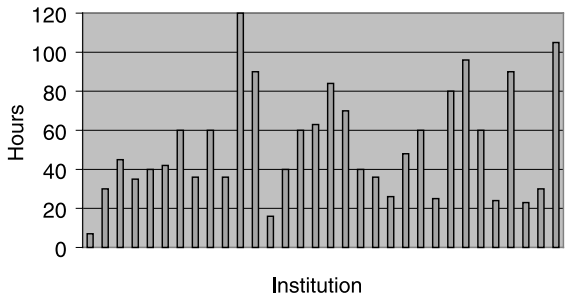

Figure 2. Lecture hours of microbiology undertaken within pharmacy degree programmes ($n = 32$).

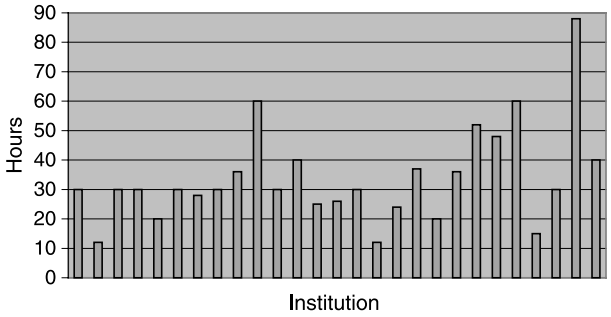

Figure 3. Lecture hours of molecular biology undertaken within pharmacy degree programmes ($n = 27$).

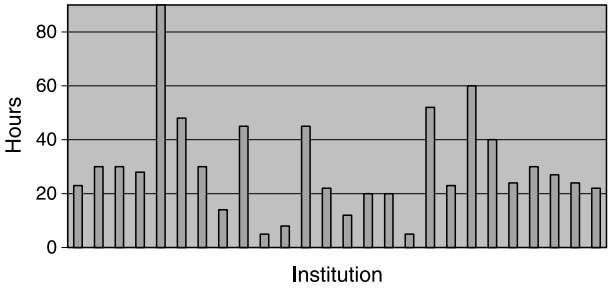

Figure 4. Lecture hours of pharmaceutical biotechnology undertaken within various pharmacy programs. (Although 33 pharmacy programs indicated inclusion of such courses, only 26 provided clear details of number of course hours delivered).

deviation of ±16.4 was evident, with the lowest reported lecture load being 12 lectures, while the highest lecture load reported was 88 h (Figure 3). In 15 cases molecular biology was taught as a stand-alone subject, while it was taught as part of a combined subject in 13 cases. Within an additional two pharmacy programs it was offered as a stand-alone elective subject. It was taught mainly in third year (14 programs). Five programs taught it as a first-year subject, another five in second year. It was taught at fourth-year level in six programs. Only two programs taught the subject over 2 years: first and second year (one program) and second and fourth year (one program).

Discussion

The survey included preliminary questions pertaining to biochemistry, microbiology and molecular biology as these three disciplines largely underpin modern pharmaceutical biotechnology. The vast majority of biopharmaceuticals are protein-based and basic details of protein structure, function, purification and characterization are generally addressed within biochemistry courses. Several nucleic acid-based biopharmaceuticals are in clinical trials for purposes of gene therapy and antisense technology, and the future importance of this class of therapeutic substance is likely to grow very significantly. Again, biochemistry courses encompass basic structural, functional and analytical aspects of nucleic acids. An understanding of microbiology is essential to pharmaceutical biotechnology as over half of all such products are now produced in engineered microorganisms (*Escherichia coli* and *Saccharomyces cerevisiae*). A basic knowledge of microbial biochemistry, physiology and issues such as microbial fermentation technology is therefore required. Recombinant DNA technology encompasses the development and production of virtually all biopharmaceuticals and a sound knowledge of the basic principles of molecular biology is, therefore, of fundamental importance in the context of pharmaceutical biotechnology.

While all programs surveyed did provide courses in these three subject areas, the variation in duration and positioning within the degree program is notable (Figures 1–3). This is likely due in large part to differences in emphasis between different degree programs, reflecting perhaps particular research strengths (or weaknesses) within specific pharmacy departments/faculties. However, in some instances significant apparent differences may also occur due to differences in the structure and/or naming of individual subjects. For example basic molecular biology is covered in some biochemistry courses and immunology is taught as part of some microbiology courses.

Pharmaceutical biotechnology

Seven of the 40 respondents indicated that students on their pharmacy programs do not take courses in pharmaceutical biotechnology. Given the central importance of biotechnology products within the modern pharmaceutical sector this number (representing 17.5% of programs surveyed) is surprisingly high, although a similar finding has been reported in the past (Calis, 2001). In all but one of those cases however, the programs include courses in molecular biology. It seems likely that some basic aspects of pharmaceutical biotechnology would be included in this subject. A further seven respondents (17.5% of programs surveyed) indicated that their programs includes pharmaceutical biotechnology, but offer it as an elective as opposed to a core subject. Therefore, only just under two-thirds (65%) of pharmacy programs surveyed taught pharmaceutical biotechnology as a core course subject to its students.

The mean number of lecture hours of pharmaceutical biotechnology courses undertaken was 29.9 h, with a large standard deviation of ±18.6 (Figure 4). The course is mainly taught in fourth year (11 programs) or in third year (nine programs). In one case it is taught at second-year level and in three cases it is taught in the final year of a 5-year program. The positioning of dedicated courses in pharmaceutical

biotechnology within the final 2 years of pharmacy programs is logical in that students will by then have undertaken basic courses in biochemistry, microbiology and/or molecular biology. These are, as previously discussed, effectively pre-requisites to courses in core pharmaceutical biotechnology.

The survey also revealed that, in the vast majority of cases (31 of the 33 relevant programs), pharmaceutical biotechnology courses are delivered by pharmacy faculty members who hold appropriate experience in the area. Only in two cases was such a course service-taught from outside the pharmacy department/faculty. In a number of instances some detail of the "appropriate experience" held by faculty was provided. This ranged from faculty members with original expertise in small molecule pharmacy that have expanded their interest into pharmaceutical biotechnology, to staff members holding PhDs in core molecular biology or protein chemistry and, in three cases, with coupled relevant industrial experience. Traditionally the majority of individuals with research or teaching expertise relevant to the biopharmaceutical sector tended to have a strong background in either molecular biology/biotechnology or in traditional pharmacy, but not in both. However, as pharmaceutical biotechnology matures as a discipline in itself increasing numbers of individuals with a far more equal balance of both "pharmacy" and "biotechnology" expertise and skill sets are coming on stream. Overall such individuals would likely devise and deliver more balanced, seamless and integrated courses in pharmaceutical biotechnology.

The survey also revealed that 11 of the departments undertaking courses in pharmaceutical biotechnology run associated laboratory practicals, whereas no laboratory component is included in the case of 15 courses. Laboratory practicals are helpful in reinforcing theoretical concepts and in training undergraduates in appropriate analytical and other laboratory methods. It is unsurprising however that the majority of pharmaceutical biotechnology courses are devoid of a laboratory component. Most appropriate laboratory practicals would likely be technically complex, time-consuming and generally would require the use of highly sophisticated analytical equipment of a type not immediately available in many traditional pharmacy departments. However, as pharmaceutical biotechnology continues to grow in relative importance, the development and inclusion of an appropriate series of related laboratory practicals seems increasingly desirable.

Resources and syllabus

Twenty-eight of the survey respondents provided some detail of books or other resources used to underpin the teaching of pharmaceutical biotechnology. Of these four relied totally upon in-house generated course notes as well as pertinent (but unnamed) reviews. Five of the respondents listed textbooks in their national language (e.g. three of the Polish respondents listed Chmiel and Grudzinski's "Biotechnology and chemistry of antibiotics" (1998, in Polish) while two of the German respondents listed "Pharmazeutische biotechnologie" by Kayser and Muller (in German). The majority of remaining respondents listed two or more textbooks, which were generally focused upon broad aspects of biotechnology, cell or molecular biology. Examples include: Glick, 1998, *Molecular Biotechnology*, ASM press, USA; Old and Primrose, 1994, *Principles of Gene Manipulation*, Blackwell scientific publications, UK; and Alberts et al. 2002, *Molecular Biology of the Cell*, Garland science. The exact profile of textbooks listed varied significantly from response to response and few appeared in more than two responses. It was also interesting and surprising to note that only a minority of respondents listed textbooks, which focus specifically upon pharmaceutical biotechnology. These were: Crommelin and Sindelar 2003, *Pharmaceutical Biotechnology*, second edition, CRC press, USA (10 respondents); Walsh 2003, *Biopharmaceuticals, Biochemistry and Biotechnology*, J. Wiley and sons, UK (three respondents); and Zito 1997, *Pharmaceutical Biotechnology*, second edition, Technomic publishers, USA (one respondent).

As in the case of reading material, the syllabi details that were provided also varied quite significantly. Twenty-four survey respondents provided such details. The details provided by individual responders varied from the use of several key words or bullet points to more detailed replies of two or more paragraphs. A summary of the responses provided is provided in Appendix 2. A marked variation of syllabus content from institution to institution was also evident. Most courses appear to emphasize a number of subtopics within the area of pharmaceutical biotechnology. In this context it is somewhat surprising that only a minority of respondents (5 out of 24; Appendix 2) specifically included formulation or delivery of biopharmaceuticals as part of their course description. These topics have always been core to pharmacy and both the formulation and delivery of macromolecular biopharmaceuticals provide unique challenges in comparison to small molecule drugs. It is of course possible and perhaps likely that formulation and delivery of these drugs is considered in more of the pharmacy programs than Appendix 2 implies, either as part of dedicated modules in pharmaceutical biotechnology or in alternative modules that focus more generally upon drug formulation and delivery. The literature contains many excellent references in the context of this topic (e.g. Frokjaer, 2000; McNally, 2000; Orive, Hernandez, Gascon, Dominquez-Gil, Pedraz, 2003; Frokjaer & Otzen, 2005).

A full and comprehensive treatment of the biopharmaceutical field appeared lacking in a significant proportion of cases. This may reflect the profile of experience, teaching and research interests of faculty within colleges of pharmacy. Additionally undergraduate pharmacy programs already cover a great deal of material. Inclusion of significant new courses in areas such as pharmaceutical biotechnology may only be achievable by significant reduction in the content of other subjects, which may not always be practical or desirable from an educational or training perspective.

Eight of the responses included details of basic molecular biology (e.g. gene isolation, cloning and expression) presumably indicating that, within these courses, this material was not taught as part of an earlier biochemistry or molecular biology course, but as part of a pharmaceutical biotechnology course. Virtually all responses mentioned recombinant protein therapeutics which, given their prominence as modern biotechnological medicines, is not unsurprising. Some listed specific protein-based therapeutic types such as recombinant vaccines, hormones and monoclonal antibodies. Again, these are amongst the most prominent sub classes of biopharmaceutical. Most responses also included reference to gene therapy. Given the likely future prominence of this class of biopharmaceutical, this is to be expected. Elements of upstream and downstream processing were also mentioned in several syllabi, while some also mentioned protein stability, formulation and delivery. Genomics and proteomics was specifically mentioned by several respondents, although the significance of these technologies to the modern drug discovery process is such that they are likely included to some degree at least in virtually all modern pharmacy programs.

While consideration of pharmaceutical biotechnology syllabus details was an important part of the survey, it represented only one of 13 questions asked (Appendix 1). However, from the replies received, it is obvious that more detailed consideration of what should be included in basic pharmaceutical biotechnology courses taught to undergraduate pharmacy students is required, within Europe at least. This issue has been considered by various authors to date (Hudson, Lubawy, & Knapp, 1990; Speedie, 1990; Manning & Mitchell, 1991; Calis, 2001; Walsh, 2001).

Conclusions

The survey reveals significant variation in duration and, to a lesser extent, exact year of placing of courses in biochemistry, microbiology and molecular biology in European pharmacy degree programs. Although these subjects underpin both theoretical and practical aspects of pharmaceutical biotechnology, they all have broader aims and objectives in the context of undergraduate pharmacy programs. As such, the variation recorded may not be significant in the specific context of pharmaceutical biotechnology. The important issue is that these courses are taken prior to (or at least concurrently with) courses in pharmaceutical biotechnology. In some cases, molecular biology is treated as part of pharmaceutical biotechnology, which is perfectly legitimate as long as it is not the sole focus of a pharmaceutical biotechnology course. The variation in duration, and in particular in syllabus details of pharmaceutical biotechnology is potentially far more significant. Given the central and growing importance of the biopharmaceutical sector it appears timely to consider this issue in more detail

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Appendix 1: Pharmaceutical biotechnology questionnaire

Background questions:

1 How many lecture hours of *biochemistry* do your students undertake and in what year of study? ——
2 Is *biochemistry* taught as a stand-alone subject or is it included as part of a larger subject? —
3 How many lecture hours of *microbiology* do your students undertake and in what year of study? —
4 Is *microbiology* taught as a stand-alone subject or is it included as part of a larger subject? —
5 How many lecture hours of *molecular biology* do your students undertake and in what year of study? —
6 Is *molecular biology* taught as a stand-alone subject or is it included as part of a larger subject? —

Pharmaceutical biotechnology:

7 Do your students take a course in pharmaceutical biotechnology? —

If so:

8 Is it a compulsory or an elective subject and in what year is it taught? —
9 How many lectures in total? —
10 Is there a laboratory component and if so can you provide details? —
11 What books/other resources do the students/lecturers use? —
12 Who teaches the course? (e.g. a member of the pharmacy dept. with industrial/research experience in pharmaceutical biotechnology, a lecturer from outside the pharmacy department, etc.) —

13 Please provide a description/syllabus of the topics covered in your pharmaceutical biotechnology course:

Appendix 2: Key word summary of pharmaceutical biotechnology syllabi outlined by the 24 survey respondents who provided such details

Respondent	Key word syllabus summary
1	Gene technology and regulation. Gene transfer and expression. Genomics and proteomics. Recombinant protein therapeutics. Gene therapeutics. Relevant drug delivery formulations
2	Expression of recombinant proteins in various expression systems. Downstream processing. Cell culture.
3	Traditional biotechnology products; antibiotics and hormones. Downstream processing. Biocatalysis and biotransformation. Immobilized cells and microorganisms. Enzymes in biotechnology. Recombinant drugs. Vaccines. Monoclonal antibodies. Gene therapy. New trends; genomics and proteomics.
4	DNA and RNA technology. Peptides and proteins and therapeutic delivery. Gene delivery systems. Gene therapy and antisense technology. Vaccines and monoclonal antibodies.
5	New therapies. Drug discovery methods. Antibiotics, vitamins and amino acids. Protein and nucleic acid drugs. Safety and environmental aspects.
6	Protein production by recombinant means. Protein purification and formulation. Range of protein based biotechnology product. Gene therapy and antisense technology. Antibiotics and vitamins.
7	Molecular biology. Expression systems. Downstream processing. Formulation. Examples; insulin growth hormone, etc. Vaccines. Antibodies. Steroids. Vitamins and antibiotics.
8	Protein structure and analysis. Protein pharmacokinetics. Fermentation. Protein purification and formulation. Drug delivery. Regulatory aspects.
9	Peptides, proteins and recombinant DNA therapeutic products. Isolation, characterization and formulation of protein drugs. Commercially available products. Monoclonal antibody technology. Gene therapy and therapeutics. Plant biotechnology and production of therapeutic protein in transgenic plants. Good manufacturing practices in biotechnology. Production plant and equipment. Small biological molecules in pharmacy.
10	Protein and peptide stability. Stability studies of biotech drugs. Delivery of biopharmaceuticals.
11	Biotechnology in drug development. Developments in gene therapy and pharmacogenetics.
12	Isolation, characterization and analysis of nucleic acids; hybridisation techniques. Nucleic acid modification. Cloning vectors. Cloning procedures. Phage display technology.
13	Recombinant DNA technology as applied to microbes, plants and animals. Overview of a selection of drugs produced by biotechnological means.
14	Introduction to biotechnology. Medically important therapeutic proteins. Engineering antibodies for therapy. Biotechnology in vaccine development. New diagnostics; application of recombinant DNA technology and antibody technology.
15	Recombinant DNA products. Production of vaccines and other immunologicals. Biotechnology in drug targeting. Oligo and polynucleotides as pharmaceuticals.
16	Therapeutic proteins and enzymes. Therapeutic antibodies. Heterologous expression and production of therapeutic proteins. Engineering and modification of therapeutic proteins.
17	Basic molecular biology. Gene therapy and antisense technology. Production of recombinant therapeutic proteins. Protein engineering. Monoclonal antibodies. Phage display technology. Non-recombinant products. Antibiotics. Genomics, proteomics and bioinformatics. Cloning technology
18	Cell biology and basic molecular biology. Culture of microbial, insect and mammalian cells. Bio-analysis of proteins. Production of biotech drugs. Downstream processing. Formulation and pharmacokinetics of protein drugs. Gene therapy. Transgenics and xenotransplantation. Vaccines. Bioinformatics. Patent and drug regulation. Specific case studies of approved biotech drugs.
19	Pharmaceuticals. Pharmacology. Clinical chemistry. Anatomy, physiology, microbiology, molecular biology.
20	Molecular biology. Recombinant proteins. Production of biotech products. Pharmacokinetic and pharmodynamic aspects. Drugs produced by biotechnology.
21	Protein stability and degradation. Preformulation studies. Biopharmaceutical delivery routes. Formulation and methods of sterilization. Non-conventional dosage forms. Drug delivery systems. Examples of commercial products.
22	Plant, animal and microbial production systems. Immobilized biocatalysts and biotransformation. Molecular biotechnology. Antibiotic production. Antibiotics and their purification.
23	Production of biotechnology products. Formulation. Protein and gene therapy based products. Genomics and proteomics.
24	Biochemical engineering and production of drugs and fine chemicals. Genomics and proteomics. Production, purification and marketing of antibiotics, enzymes, vitamins, hormones, growth factors. Antibiotics. Pharmacokinetics and pharmacodynamics. Intellectual property issues.