

“Better Safe Than Sorry”

A detailed look at how new prescription drug reimportation legislation makes safety the top priority

Safety and Drug Reimportation: An Overview

In most major Western nations, prescription drug reimportation is a way of life. In these countries, the belief that consumers should have access to the best prices in the world for medications is not up for debate. Unfortunately, this is not the case in the United States. Despite this nation's adherence to capitalist principles of free trade in nearly every industry, Americans remain one of the few populations that are completely prohibited from utilizing that market to find fair prices for medicines – the most important of all products.

Last week, Congress finally acted to change this, with both houses of Congress overwhelmingly passing legislation to allow American pharmacists, wholesalers and distributors to reimport FDA safety approved prescription drugs from other countries at the lower prices offered there. In the legislation, a strict safety regime would be established to ensure that any drugs coming into the United States are as safe as any drug currently being offered here. The regime is loosely based on well-established systems in England and other EU countries.

In response, the pharmaceutical industry has launched a multimillion dollar advertising campaign aimed at frightening people and killing the legislation. In these radio, television and newspaper advertisements, the industry falsely claims that the legislation would subject the United States to a wave of counterfeit drugs with deadly effects. The following report details how the legislation would prevent this from happening, and how safety standards have not been diminished in industrialized countries which allow for the free trade of prescription drugs.

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SAFETY AND REIMPORTATION: A STEP-BY-STEP GUIDE

Under current law, prescription drug reimportation is permitted – but only by the drug manufacturers themselves. Though the industry makes it seem as if reimportation would bring entirely new threats that we are not prepared for, these threats already exist and are being regulated. Currently, more than 80% of all drug ingredients in the U.S. are imported from other countries and are strictly regulated. In other words, much of the infrastructure to validate the integrity of pharmaceuticals is already intact. The new safety regime in this bill simply expands those safety measures to better ensure that imported drugs are FDA-approved and meet FDA standards.

Step 1: Under current law, the drug is manufactured in a facility that complies with all FDA requirements for Good Manufacturing Practice (GMP). The drug is tested for quality and packaged

Step 2: Drug is sent abroad to a subsidiary, wholesaler, or pharmacy as is currently practiced.

Step 3: Any wholesaler in possession of the drug must be registered with the Secretary of Health and Human Services and is subject to inspection

Step 4: Since reimportation is legal, a US importer seeking to find a better price for a particular prescription drug can shop around the world market instead of endlessly negotiating with a manufacturer for a small discount.

Step 5: If the drug is coming from Canada, for instance, it is likely that it will be 40-50% cheaper than the US-sold, identical product.

Step 6: The batch of drug is sent to the US importer.

Step 7: Upon arrival in the US, the batch must be tested by an accredited, third party lab (monitored by the FDA) that assures it is identical in all respects to the non-exported brand - thus safe for entry.

Step 8: Intellectual property rights are protected.

Step 9: All labeling and records pertaining to the chain of possession must be provided and checked by the manufacturer.

Step 10: The importer pays for the testing and reimburses the manufacturer for the reasonable costs associated with record keeping and labeling.

Step 11: All Americans reap the benefits of the world market when their prescription drugs are provided at substantially lower prices.

CASE STUDY: BRITAIN VS. THE PROPOSED U.S. SYSTEM

Britain is widely regarded as having one of the highest quality health care systems in the world. In the latest World Health Organization report, the British health care system was ranked number 9 in the world. In comparison, the United States was ranked 15. In Britain, the average price of prescription drugs is 35% lower than in the United States. One of the ways Britain is able to keep costs relatively affordable is through the use of parallel importation, or reimportation. Their system has employed a safety testing regime of imported medicines that is much like that included in the proposed reimportation legislation in Congress. In fact, in some instances, the proposed regime in the bipartisan legislation is even stricter than in Britain.

	Reimportation into the United States	Reimportation in the United Kingdom
Is Reimportation Legal?	Reimportation is legal for all products except FDA-approved prescription drugs.	Reimportation has been legal and in practice for pharmaceuticals since 1970. The 1992 TRIPS trade agreement certified that reimportation cannot be stopped.
What is the difference in prescription drug prices?	<i>The British pay 36% less than Americans</i>	
Does the government control prices?	Certain federal programs like Medicaid and the VA regulate prices for their programs' beneficiaries.	Manufacturer retains some or all of the price leverage, as do other European countries like Germany and the Netherlands.
Under reimportation, how is the public protected from counterfeit products?	Under the Reimportation language being considered in Congress, the FDA has the authority to implement a system by which safety is ensured.	The British government strictly enforces the safety of its drug supply through their FDA-equivalent organization, the Medicines Control Agency (MCA)
Are the drugs being reimported the same as the drugs dispensed today?	The legislation being considered ensures that all products reimported are chemically identical to those not exported. (A higher standard than Britain)	All products reimported to Britain are therapeutically identical to non-exported drugs. Extensive programs have been put in place by the MCA to report and track potential counterfeit drugs.
Can anybody reimport prescription drugs?	Not under the proposed legislation. Only licensed importers may import and are subject to inspection by FDA at any time.	No, all importers must be licensed and are subject to regular inspections by the Inspection and Enforcement Division of the MCA.
Is there an audit trail indicating where the drugs have been?	Yes, in the legislation a complete paper record must accompany all shipments that can be traced directly back to the manufacturer in the US.	Yes, a complete record of all movements is established traced back to the manufacturer. Each shipment must be certified by the government as to its proper storage and handling.
Does each shipment have to be tested upon entry to ensure its safety?	Yes, under the bill, batch testing must establish chemical equivalency and assurance that the product has not degraded or been handled improperly.	Yes, each reimported product is tested against predetermined and agreed quality assurance standards set by the MCA.

EFFECTS OF REIMPORTATION IN BRITAIN

The effects of prescription drug reimportation has been the subject of various hearings before the British Parliament. At each hearing, the drug industry has claimed that reimportation will allow an overflow of deadly counterfeit products to enter the British market. That has not been the case.

COUNTERFEITS “VIRTUALLY UNKNOWN” IN BRITAIN

The British Medicines Control Agency (MCA) – the equivalent of the FDA in the United States – is on public record is in its belief that counterfeiting and piracy within the pharmaceutical sector is not an issue. According to testimony before Parliament, MCA believes “counterfeit drugs are virtually unknown” in Britain. (see testimony on page 8 and page 12)

LAST KNOWN MAJOR COUNTERFEIT IN 1997

According to testimony before Parliament, the MCA reported that the last known major counterfeit was in 1997 when a subpotent, branded product entered the market. In the ensuing investigation, it was revealed that the drugs were NOT parallel imports.

NO INCREASE IN COUNTERFEITS BECAUSE OF REIMPORTATION

Ms. Phillipa Clare works for the firm Rishworth Chase and traces parallel goods back through the supply chain to verify authenticity. When called before Parliament to give her expert opinion on whether the parallel importation of prescription drugs had increased the amount of counterfeit drugs entering Britain. She said there is a “low percentage of any counterfeits coming into the United Kingdom or any parts of the European Union.” She added, “I do not think there has been a marked increase or decrease in counterfeit drugs” because of parallel importation (see page 21 for full testimony).

NO DECREASE IN R&D BECAUSE OF REIMPORTATION

The pharmaceutical industry has claimed that reimportation would force a major decrease in research and development, meaning there would either be less drugs coming to market or a loss of quality in medicines. However, as Mr. J. Barker of the Association of Pharmaceutical Importers said before Parliament, no company in Britain “has ever produced evidence” supporting that claim. “If they would like to produce that evidence, then we would be happy to consider it, but at this time the statement has often been made...and never once was any evidence produced...As you well know, if you look at the published financial figures of the pharmaceutical companies, they are all increasing their profits year on year. They claim—they claim—to be increasing their R&D expenditure, so quite how they then argue that their R&D budget is at risk, I do not follow.”



TUESDAY 11 MAY 1998
HOUSE OF COMMONS
SELECT COMMITTEE ON TRADE AND INDUSTRY

TESTIMONY OF MR J BARKER and MR T BROWN, ASSOCIATION OF PHARMACEUTICAL IMPORTERS

Chairman

474. Good morning. A couple of weeks ago we had in the ABPI and they questioned the idea of imports being identical in all respects and they gave us examples of different appearances of parallel imported products, tablets that have been broken from larger sets and no longer have batch numbers etc. We have seen examples where the appearance of parallel imports is different from the UK version. Is it not misleading to talk of parallel imports being identical when there are examples of them varying in appearance? How do you control that process of importing? How do you control the goods going out to pharmacies and then to patients which do not have the instructions in English, are not part of the proper pack, do not have bar codes or do not have sourcing information? How do you deal with that? Do you recognise it as a problem and if you do, how do you deal with it with regard to your people?

(Mr Barker) Good morning. May I start by apologising for the sound of my voice. Unfortunately it is only in the last couple of months that it came back to me. This is going to sound very tedious but it will be brief, I can assure you. The trachea broke into two so I could not speak at all for eight months. Thanks to the National Health Service and an absolutely brilliant surgeon in Birmingham, he reconstructed that trachea so I can now babble away to you to my heart's content this morning. I do apologise but I only have one vocal cord. In answer to your question, the Association does not accept the contention which was apparently made to you by our colleagues in the ABPI. You have to understand that as far as pharmaceuticals are concerned, and I am sure you know, it is probably the most heavily regulated industry of all industries, quite rightly so, because of course we are dealing with public health. It is a regulatory side largely governed by the Medicines Control Agency within the Department of Health that confirms that all parallel imports, products which are brought in from another Member State within the European Union, are therapeutically identical. So far as the ultimate patient is concerned, the key is whether the product is therapeutically identical not whether it is the same colour, the same shape or whether the packaging is the same. Members of the ABPI manufacturing industry have for a long time attempted to hinder the parallel trade by quite deliberately making tablets of different colours, deliberately making them a different shape and deliberately using different packaging. That is a conscious attempt to impede the trade to which they will privately admit. We have to live with that situation and you have to remember that before we can place a product on the market we have to send a sample of that product, the new packaging if that is what we are going to use, a copy of the patient leaflet, to the regulatory authority. It all has to be approved. No product can go onto the market unless that approval has been obtained and no product goes onto the market and no approval would ever be obtained for a product the constituent packaging elements of which were not in the English language. I have no evidence to suggest that any product which is not packaged in the English language comes onto the British market. I am sorry, but I have no evidence of that.

475. We have had evidence relating to the drug Zoladex, which apparently is used in the treatment of Parkinson's Disease and the Parkinson's Disease Society have said to us that there have been instances where drugs like Zoladex have been made available to their patients and the instructions have been in Spanish. They say this is not unusual. Are there other sources of parallel importing of medicines in the United Kingdom apart from your members?

(Mr Barker) The answer to that question is yes. You and I could both go out tomorrow and start to import medicines into this country, but that is all we could do. The question is not whether we could import, but whether we could put into the supply chain, in other words distribute. That we could not do unless we were authorised by the Medicines Control Agency so to do. In order to get that authorisation, we would need a Manufacturer's Assembly only licence as it is known, we have to comply with certain standards. One of those is that we must employ a Qualified Person. That Qualified Person, who is not in fact employed by the company but is answerable direct to the Medicines Control Agency, has to be satisfied that every product which goes out is in accordance with the Terms of the marketing licence, in other words it has been packaged correctly, etcetera. That is mandatory. In the event that there is an example of a product which is coming into the market which has not gone through that quality control procedure, which incidentally is far greater for the parallel importer than applies to the manufacturer, if that

happens—

476. In what ways is it more difficult?

(Mr Barker) Let me explain by way of one example. If we take Bayer as such an example, the large German pharmaceutical group which manufactures ADALAT, which is a hypertension reduction drug, ADALAT is only made in Germany. There is no manufacturing facility here at all. A truck can leave Bayer's property, Bayer's manufacturing plant and come to the UK with no checks whatsoever and the product can be immediately placed onto the market. If I want to bring a truck in with the product from the wholesaler nextdoor to Bayer's plant in Germany, it has to be checked as soon as it comes into this country, it has to go through the quality control system, it is liable to be inspected by the MCA, the product is liable to be analysed in the Edinburgh laboratory, etcetera. Consequently there are more checks for the importer to ensure, or try to ensure, that products of inferior quality or whatever never come into this market. Indeed when we look at products of inferior quality, when we look at counterfeit products, there have only ever been two examples of counterfeit pharmaceutical products identified and in both cases members of my Association identified them.

Mr Butterfill

477. May I just say that I personally have had drugs prescribed for me which have arrived packaged with Spanish leaflets with them and instructions in Spanish. This was the drug Zocal, which you probably know. I have also had experience of the product arriving partly in the original pack and part of it being snipped off so you do not always see the batch number, which is the other complaint. Fortunately in my case it is a drug with which I am familiar, but if I had been a first time user of that drug and the instructions were in Spanish, I might have had difficulty.

(Mr Barker) You would indeed, I can imagine, have had some difficulty. As you will appreciate, you have recognised that the responsibility for dispensing the drug to you lies with the pharmacist. The pharmacist should not have dispensed to you in the event that there was a pack, as you apparently had, with a non-English leaflet inside it. He should not have dispensed it to you. He has additional leaflets which are always made available to pharmacists.

478. Would he have known? Would he always open the pack and find out what was in there?

(Mr Barker) It depends on the pharmacist because there are some pharmacists who never use the outer carton, that is the manufacturers carton; even when a member of my Association repackages in his own in-house carton he will still destroy that and repackage in his own carton with his own label. What you would have found, I would submit, with your example, is that there would have been a label in English on that outer carton. There would have been a label on the blister. The fact that you did not have a leaflet in English is deplorable and that should not have happened. One of the responsible persons within the chain—we are responsible for that—is also the pharmacist. If you like, he is a fallback check. He does have supplies of leaflets, so if one has gone through the system, such that the foreign leaflet has not been taken out, which is highly unusual I must say in the millions of packs which are dispensed, if that has happened he would have a replacement leaflet he could insert.

479. Do you think there are any consumer benefits of parallel imported medicines?

***(Mr Barker)* The consumer benefit, if by consumer you mean patient, the ultimate consumer—**

480. Yes, the ultimate consumer.

***(Mr Barker)* The patient, because as you of course know, the consumer is a strange animal in the pharmaceutical world. As far as the patient is concerned, the prime benefit comes back through the clawback through the price containment that parallel import products have on the price of product.**

481. Is that right? We get the impression that the profit goes to the parallel importer and maybe the pharmacist but neither the NHS nor the NHS's patients, the general public, actually benefit from this process.

(Mr Barker) In my opinion this is one of these misconceptions which seems to be very popular. There is unquestionably a financial benefit to the Treasury through the clawback. That is estimated to be around about two per cent, so there is a financial benefit there which can be quantified and is quantified. What is more difficult to quantify is the fact that the parallel imported product does on occasions mean that the domestic manufacturer is unable to apply for a price increase. It can on occasions encourage him to discount, as he often will do, the domestic product in the United Kingdom. That does happen.

482. We have not been able to get any evidence of that. Can you provide some evidence of that? We have seen that assertion from you and it is something we have heard before, but getting hard evidence sounds more difficult. Could you supply us with some clear evidence of where parallel importing has resulted in price decreases?

(Mr Barker) I would prefer to do that in writing.

483. We are very happy to have that.

(Mr Barker) It would be on a confidential basis. I can supply evidence which firstly shows products where prices have actually been reduced and secondly I can supply evidence of where we have been offered products at a lower price to encourage us to market or to supply the domestic version as opposed to the imported version.

484. The other thing that many of the drug manufacturers claim is that their research projects are going to suffer if these parallel imports go on because they will not be able to fund the very expensive research in which they are engaged. You say that there is evidence to show that the reverse is actually the case. Can you elaborate on that?

(Mr Barker) I do not think, with respect, I said the reverse is the case. What I in fact suggested was that there is no evidence to support the contention by the manufacturers that their R&D budget has been or is likely to be affected in any significant sense at all by the parallel trade. As you well know, if you look at the published financial figures of the pharmaceutical companies, they are all increasing their profits year on year. They claim—they claim—to be increasing their R&D expenditure, so quite how they then argue that their R&D budget is at risk, I do not follow.

485. They have not all increased their profits.

(Mr Barker) The majority.

486. There are one or two who have got into quite spectacular difficulty.

(Mr Barker) They are the exception, not the rule, with the greatest respect.

487. You do not think that this sort of claim that they need some sort of guarantee of return on their investment is one which stands up to any detailed scrutiny.

(Mr Barker) I am not aware that too many sectors generally have any such guarantees. I am not quite sure that I understand why the pharmaceutical sector needs to be singled out for that kind of guarantee.

488. They do have certain problems, do they not? You have said yourself that the testing which goes on and the licensing arrangements are fairly severe.

(Mr Barker) Accepted.

489. I am not holding a candle for them. I am trying to tease out from you evidence that will support the statements you are making to us.

(Mr Barker) Was that a question? I am sorry.

490. Yes, it was. I am sorry if it was not clear.

(Mr Barker) Could you repeat the question?

491. I am concerned that you suggest that it would not affect their ability to conduct research in any way if parallel importing were to go on in an unrestricted manner, whereas they would say that they need at least the reliability of a market in which to operate. You are suggesting that really that does not stand up. Why does it not stand up?

(Mr Barker) What I am suggesting is that I have yet to receive any evidence at all that their R&D budget has been affected and significantly affected by the parallel trade. Nobody has ever produced that evidence.

492. Presumably it could be.

(Mr Barker) If they would like to produce that evidence, then we would be happy to consider it, but at this time the statement has often been made. It was made in the Bannerman round table conferences for three consecutive years and never once was any evidence produced.

(Mr Brown) Is not the point that the burden of proof lies firmly with them rather than with us? If they made the statement, they need to establish that it is the case.

Chairman

493. Is it the truth that the major source of parallel imports are generic drugs rather than R&D based ones? Would that be true?

(Mr Barker) No. I am not quite sure where that information has come from. The majority of the parallel trade is concerned with branded products rather than generic products. I cannot speak for the importation of generic products through the parallel trade route. It is true that some products are brought into this country as brands, but are then put into the supply chain as generics, yes. But I am not aware myself of any significant volume of generic products coming into the parallel trade route.

Mr Berry

494. Earlier you commented on the counterfeit pharmaceuticals issue. Am I right in understanding that you are saying that those who argue that parallel importing has led to an increase in counterfeit pharmaceuticals in the UK are exaggerating the problem? Is that how I understood you? May I put it more neutrally? Do you think that parallel importing has led to an increase in the number of counterfeit pharmaceuticals in the UK market?

(Mr Barker) As far as I am concerned, I am only personally aware of two examples of a counterfeit product. The MCA as the regulatory authority are on public record as stating that counterfeit in pharmaceuticals is not an issue for the United Kingdom.

495. Could I ask you to comment on the global situation because the ABPI have expressed concern that counterfeiting globally is increasing. Do you share that view?

(Mr Barker) I cannot answer the question because I do not have the knowledge to answer it. The only observation I would make to that of course is that the pharmaceutical industry itself and the manufacturing side of it has, I would suggest, a very decided responsibility in this area. If they cannot control their own raw material actives, and so on ... I know that in the extreme case of course you will even have products with no active ingredient in at all, but it is primarily their responsibility rather than anybody else's.

Mr Hoyle

496. What conditions make the UK a major source for parallel exports? Is it just that prices are lower than in countries like Denmark or Germany?

(Mr Barker) Yes.

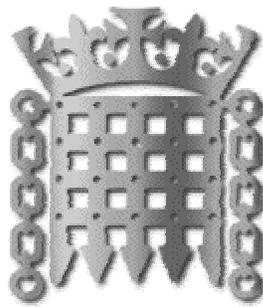
497. It is as simple as that.

(Mr Barker) Yes.

498. No other conditions which would affect it.

(Mr Barker) The only other factor—and it is a factor of course—is that in this country, as we are all painfully aware, our ability to speak any language other than English is not high, whereas of course if you go to Germany, Denmark, Holland and so on, English is very widely spoken and understood, with the consequence that all the problems associated with a foreign language are not so acute in countries like Denmark, Holland, Germany.

Chairman: Thank you very much, that is very helpful. I think you indicated it might be appropriate to reply to us in writing on a couple of points and we should be happy to receive that. Thank you very much for your time and your trouble this morning.



TUESDAY 11 MAY 1998
HOUSE OF COMMONS
SELECT COMMITTEE ON TRADE AND INDUSTRY
MEMORANDUM SUBMITTED BY THE ASSOCIATION OF PHARMACEUTICAL IMPORTERS

1. BACKGROUND

1.1 Introduction to the API

The API is the professional association representing almost all those companies engaged in the parallel pharmaceutical distribution industry (PPDI) within the United Kingdom. The Association is also a founder member of the European Association of Euro-Pharmaceutical Companies (EAEPC), the European federation of the national associations of companies within the PPDI of certain EU member states.

To be eligible for membership of the API, companies must be in possession of a Manufacturer's (Assembly Only) Licence and a Wholesalers Dealers Licence, both of which are issued by the Medicines Control Agency (MCA), the regulatory authority within the Department of Health.

It is the possession of the Manufacturer's (Assembly Only) Licence which differentiates members of the PPDI from full line wholesalers such as Unichem Alliance, AAH (a unit within Gebe of Germany) and selected regional wholesalers, all of whom are likely to be members of the British Association of Pharmaceutical Wholesalers (BAPW) as well as from companies known as short line wholesalers). The difference between BAPW members and short liners when compared with those companies who are part of the PPDI is the fact that the former stock over 15,000 product lines, short liners around 4,000 items whereas the latter hold in the region of 7,000 to 8,500 comprising imported branded prescription drugs, generic drugs, a limited range of domestic branded products and a few selected non-prescription items.

1.2 The nature of the pharmaceutical market

A considerable proportion of the total volume and value of the pharmaceutical drug bill is accounted for by imports made by members of the research based industry themselves. Estimates suggest that over 50 per cent in value terms is probably near the mark: as an example, Bayer of Germany has no manufacturing facilities in the United Kingdom so that its total product range has to be imported.

The prime reason for the PPDI lies in the absence of price harmonisation of pharmaceutical products within the European Union. Such harmonisation seems unlikely for the foreseeable future.

(It is frequently contended that member countries in the northern part of Europe subsidise those in the south: it is difficult to argue that this achieves the social objective of wealth distribution as French and Belgium prices, when compared to those of the Netherlands and Germany, are proportionately much lower than any variances in relative national GDP.)

1.3 The value of the market comprising the PPDI

Collectively member companies of the API account for almost 95 per cent of the value of imported licensed pharmaceuticals sourced solely from within the EU. Various estimates of the value of the trade circulate within the market, but there is no definitive figure available even from such independent statistical compilers as Intercontinental Medical Statistics (IMS), Taylor Nelson Sofres (TNS) or PI Monitor. One of the reasons is that the Pharmaceutical Industry is unable to agree the point within the supply chain at which the valuation should be made: another reason is the wide variety of discounts given by members of the innovative industry, as part of their marketing strategies-such discounts affecting the calculations applicable to individual products. The API only issues a value figure calculated as an aggregate of the landed total cost of imported products made up of the price from the wholesaler in the source country plus carriage, insurance and freight.

1.4 The logistics of the market comprising the PPDI

It is important to remember that there are a number of key differences which distinguish the pharmaceutical market place from any other. These include:

Pricing: In all member states within the EU, it is the national government which controls or substantially influences the pricing of pharmaceutical products; only in the United Kingdom now is there some considerable control retained by the Manufacturer as the degree of government involvement by countries such as Germany and the Netherlands, which traditionally also enjoyed an element of free pricing, has significantly increased in recent years.

Product Identicalness: Licensed pharmaceutical products which are imported by members of the PPDI are identical in all respects to the branded version marketed by the Originator in the country into which it is imported. All such products require a Product Licence (PI) which is a "piggy-back" authorisation granted by the competent regulatory authority, the MCA, after extensive checks to ensure that the imported drug is therapeutically the same as the domestic version.

Consumers: The market place for prescription medicines is different to that which subsists for other products. The factor of choice is exercised by the prescriber (normally a General Practitioner), not by the consumer. The source of supply is restricted in that medicinal products for human consumption can only be obtained through a registered pharmacy. The product provider has to be a qualified dispenser, i.e. a pharmacist.

Legality: The foundation stone of the PPDI lies in the enshrined principle of Articles 30 & 36 of the Treaty of Rome, namely the free movement of goods. The subsequent framework of the industry has been built by the innovative industry in its attempts to have the trade banned through the decisions of the European Court of Justice in Luxembourg. The PPDI is supported by the EC Directorates-General IV, XV and XXIV: the position of DGIII is more ambivalent.

The United Kingdom government has traditionally claimed to maintain neutrality on the issue: however, the political clout of the ABPI has undoubtedly had an impact on its thinking.

Thus the pharmaceutical market has major differences in its characteristics when compared with other consumer sectors into which the existence of parallel trade products may subsist: the imported medicinal product is not a copy; does not vary in any respect from the original; and is manufactured normally by the Originator himself or by their licensee to the approved product specification.

Regulation: Members of the PPDI operate within a heavily regulated environment: to some extent the scope of the regulations governing their activities is understandable in that their products are destined for entry into the pharmaceutical product supply chain with the consequent implications for public health, an area which governments have traditionally seen as being one for their involvement.

The regulations presently in force for the non-Original licence holder (Marketing Authorisation) are far stricter and all embracing than those which exist for the Originator. Thus, for example, Bayer may import ADALAT Retard from Germany, which it can then immediately place in the market whereas a PPDI member importing the therapeutically identical product from Germany has to comply with a complete set of procedural rules before he can allow the product to enter the supply chain.

2. THE HISTORY OF THE PPDI

2.1 The beginnings (1970's/1980's)

The Industry can trace its history back to the 1970's when a number of entrepreneurial pharmacists ascertained that drug prices varied significantly between member states of the EEC. They established small wholesale businesses from their dispensaries, supplying other pharmacies within the local area.

The DHSS became concerned that without rules, regulations or even guidelines there was a possibility that counterfeit or low quality products might find their way onto the British market.

It was under Dutch jurisdiction, where the trade was also established in the Netherlands, that the first legal cases such as *de Peijper* (determined in 1975) went to the ECJ to determine issues questioning the apparent conflict between intellectual property (IP) ownership and free movement of goods.

The UK importers worked closely with the DHSS to produce and develop rules and regulations governing the trade, thereby ensuring the maintenance of public health standards and guaranteeing that the imported form of any pharmaceutical product was the same as the domestic version. Many of the agreed procedures in the late 1970's/early 1980's were the consequence of a non-binding Communication issued by the Commission in 1982 on parallel imports of proprietary medicinal products for

which marketing authorisations had already been granted. This Communication ([1982] OJ no. L 115/5) effectively codified the principles of the de Peijper case which outlined the obligations upon parallel importers, including the particulars to be submitted to the national competent authority and obligations in respect of batch control.

2.2 The Licensing, Inspection and Monitoring System (The early 1980's)

The resultant licensing system which is operated and enforced by the Medicines Control Agency (MCA) on behalf of the Department of Health may be summarised as follows:

1. Only approved importers meeting the necessary standards as laid down by law are licensed to import and distribute prescription medicines.
2. Before importing any pharmaceutical product, an approved importer must obtain a PL(PI) which is effectively a "piggy-back" marketing authorisation granted by the MCA: such an authorisation is only issued once the competent regulatory authority is satisfied, through a process of due diligence, that the proposed imported preparation is therapeutically identical to the domestic version.
3. Each product must be checked against predetermined and agreed quality standards as well as being subject to documentation establishing an audit trail back to the manufacturer.
4. The Inspection & Enforcement Division of the MCA undertake regular visits to the premises of all the licensed importers within the PPDI to ensure compliance not only with the terms of each and every PL(PI) licence issued but also to undertake random checks on: quality assurance standards; the audit trail for specific products; and health and safety aspects. This ensures full compliance not only with the Medicines Act 1968 (as amended) but also with the various labelling, patient information leaflets and other regulations pertinent to the industry.
5. The MCA undertakes the monitoring of medicinal products once they have been placed upon the market, maintaining the necessary records which include the reports of side effects and, where appropriate, any subsequent action.
6. The parallel importer must also comply inter alia, with:
 - pharmacovigilance and product recall obligations;
 - obligations to monitor variations in and issues relating to the validity of product licences/marketing authorisations informing the MCA when necessary.

The Inspection & Enforcement Division's role is supported by the legal requirement under Article 22 of Directive 75/319/EEC, which requires that medicinal products moving from one member state into another must be accompanied by batch control documents, complying with the laws of the member state of manufacture, or for such controls to be completed by a qualified person in the importing country. (A "qualified person" means a person who has appropriate qualifications and experience of the pharmaceutical industry. The "qualified person" is independent and responsible to the national competent authority not to the product licence holder: all product licence holders must retain the services of at least one such qualified person.)

NB: Further information can be obtained through a publication available from the MCA, "Notes on Applications for Product Licences to cover the parallel importation from EU member states of medicinal products for human use".

2.3 The Period of Consolidation (1985-1998)

Over this period, the PPDI has developed from a trade into a mature industry, employing several thousand people and increasingly embracing all countries within the EU, notwithstanding the policies followed by the innovative sector companies in their attempts to have the trade banned or at least severely restricted.

Their antipathy has meant constant attendance at the ECJ with considerable expenditure of resource, both human and financial, by not only the innovative industry but also by the PPDI. Some of the legal actions embarked upon have involved the competent regulatory authority (the MCA): such a combative approach have cost the authority considerable resource in terms of both money and manpower. There has been little attempt by the innovative pharmaceutical sector companies to justify their actions as being for the public good, and equally, no shareholders seem to have questioned the strategies either. On occasions, some companies have suggested that their research budgets have or will continue to suffer due to the existence of the PPDI but never once has this been either substantiated or qualified in the public domain. Indeed a study of their published results would indicate the contrary.

STRATEGIES USED TO TRY TO HINDER OR KILL THE PPDI:

2.3.1 Exhaustion of Rights

The apparent conflict between Intellectual Property rights, particularly Patent Rights and the Free Movement of goods, was settled by the ECJ through the development of the principle of exhaustion of rights. The pivotal point in the establishment of a common market had to be the freedom of the movement of goods, services and people throughout the EEA; as such the concept of the free movement of goods must be at odds with the intellectual property rights preventing importation. Since the

protection of innovative (and improved?) molecules or drugs is crucial for recovery of research costs incurred, the battle ground was clearly in place from inception, unless the market adopted price harmonisation from the outset. Since this latter policy would have involved government relinquishing its control of pharmaceutical pricing such an objective was hardly attainable at least in the early days: indeed it is still as elusive nowadays as it was then (see the failure of the three Bangemann Round Tables on the "creation of a single market in pharmaceuticals").

The doctrine of exhaustion of rights provides that IP rights may only be enforced to prevent importation of goods into member states of the EEA when those goods have not previously been marketed within the EEA if the owner has consented to the goods being marketed in the member state. If the owner has consented to the particular goods being placed into one member state he cannot use those rights to prevent the goods being exported from that member state to another. Thus, national boundaries cannot be used to segment the market and have effectively disappeared.

(The principal case law can be found in:

Deutsche Grammophon GmbH v Metro-SB Grossmarkte GmbH (Case 78/70) [1971] CMLR 631 Centrafarm BV v Sterling Drug: outcome-win for PPDI (Case 15/74) [1974] 2 CMLR at 503 Centrpharm BV v Winthrop BV outcome-win for PPDI (Case 16/74) [1974] CMLR 480 at 508 Merck v Stephar: outcome-win for PPDI (Case 187/80) [1981] 3 CMLR 463 Merck v Primecrown: outcome-win for PPDI (Joined cases C-267/95 and 268/95) [1997] FRS 237)

2.3.2 Exhaustion of Rights (Trade Marks)

One method that has been employed by manufacturers of pharmaceuticals to contain or prevent the parallel trade has been the registration and use of trade marks: different brand names registered as trade marks in different member states. This practice was followed with scant if any regard to the interests of the ultimate consumer who, as international travel increased in frequency often found themselves confused when confronted with the need for a repeat prescription medicinal product; it made a mockery of the claim made by the Innovative Industry to be solely concerned with public health).

If an importer, in order to market a product in the member state of importation, has to repackage the medicine with the brand name of that country (such a brand name being different to that used in the source state), then the manufacturer would rely upon his trade mark rights in the country of import to prevent the sale of the product onto the market. This was on the basis that the use of the trade mark as registered in the import country is done without consent and is therefore an infringement of the owner's rights.

However, recent legal actions brought before the ECJ by the innovative industry on this matter indicate that the exhaustion of rights applies to the use of trade marks particularly in instances where different marks can be deemed to segment or partition the market. A recent Opinion by the Advocate General would appear to take the boundaries still further apart by suggesting that if rebranding is necessary to market the goods from the country of export in the country of import then such rebranding should always be permissible provided that:

- it does not damage the Original Trade Mark;
- the importer gives notice of his intention to rebrand;
- the importer provided a sample upon request.

2.3.3 Manipulation of the Regulations

As previously noted, in order to obtain a PL(PI) an importer has to "piggy-back" the mother licence of the Originator. To do this the importer has to show the regulatory authority in the country of import that the product to be imported has the same therapeutic effect as the domestic version. There are occasions when the authority will seek information from its sister organisation in the exporting country: this may result in enquiries being made direct of the manufacturer. Responses may take a long time to obtain; meanwhile the market opportunity is slipping away from the importer.

Sometimes the manufacturer may attempt to have different formulations in different countries: if this is the case, a piggy-back licence may not be allowed. The importer has to prove that the product is the same, as minor formulation differences such as these might have a therapeutic effect. However, the manufacturer has to be careful that such a policy does not run foul of the competition provisions as they could be open to a charge of attempting to partition the market.

Small batch sizes have long been a weapon employed by the multinationals. Under the terms of a PL (PI) details of batch lots must be recorded. There have been many examples of products which have only been available in lots of 10 or 20 pieces: given that one of each lot has to be retained as a sample in case of a problem in the future and the cost of processing and larger batches is the same, such a practice can render the parallel trade activity uneconomic.

These practices are likely to continue and there is little that the PPDI can do except seek the support of the European Commission (possibly in conjunction with selected consumer groups) to bring pressure to bear upon those member states in particular where delays are frequent. Ironically, the longest delays are usually found in the regulatory authorities of the exporting, lower priced countries rather than those in the importing, higher priced countries. However, as some of those countries are now importers as well as exporters, albeit only on a small scale, this may change over the medium term.

2.3.4 Commercial Tactics

Direct supply: To avoid parallel imports, manufacturers will often supply direct to pharmacy outlets with supplies at greatly reduced prices. This commercial ploy is particularly attractive in the hospital sector as it guarantees supply of a preparation to the hospital, which the importer can never do. It overcomes the prejudice often found in hospital pharmacists who have no profit saving incentive against repackaged parallel imported goods and it has the pay-back that the product is likely to be continued to be prescribed after the patient leaves hospital by the general practitioner. This practice will continue to the benefit of the cost containment programme in the NHS and private hospitals. Thus, it is an indirect benefit brought by the parallel trade.

Agents: By employing agents who act solely for the producer, to implement a policy of direct supply, a pharmaceutical manufacturer can avoid the potential problems of the competition rules (under Articles 85/86 of the Treaty of Rome).

The principal reason why this option has had only limited use is the existence of regulations relating to commercial agents generally, particularly those covering the payment of compensation if the agency has to be terminated. Thus the practice is unlikely to be employed by the industry.

Limitation of Supply: This is an avenue presently being explored by the larger pharmaceutical companies. In essence the policy is to restrict the quantity of supplies made available to wholesalers known to export product to other member states. There is no law which requires a manufacturer to produce adequate quantities to satisfy demand, particularly in a highly regulated market place where the normal principles of free pricing have little application. However, it should be noted that DGIV have brought a case against Bayer of Germany for withholding supplies of their best seller ADALAT, a hypertension medication, in France and Spain, where the price of the product is significantly lower than in the United Kingdom, Germany, Holland and Denmark. We would expect that DGIV should win their case.

Dual Pricing: Glaxo Wellcome in Spain is pioneering a strategy of two tier pricing: a low price for their products which are distributed within the Spanish market, and a much higher price for products which are to be exported from Spain. This is presently being investigated by DGIV as it would appear to be an infringement of Articles 85/86. The evidence available would indicate that this policy will be declared to be against the competition rules of the internal market.

Appearance Differences: These are a traditional method to hinder the PPDI. The effect is greater in some member states than in others as much depends upon the dispensing practices. Where the differences relate to the outer carton only, the impact may be small in countries where the pharmacist discards the outer carton and uses his own, or where the pack is broken to comply with the prescribed amount only. However, shape and size variations are more effective as these will necessitate the pharmacist explaining to the patient that the tablet/capsule is the same medication even though the colour or shape is different. There is real prejudice against medicines originating from other countries where differences from the domestic version are manifestly obvious (notwithstanding that the patient may have consumed French cheese the previous evening with a glass of German wine and driven to the pharmacy to collect the prescription wearing Italian apparel in a Swedish motor car!) As a result some pharmacists, particularly those who prefer not to explain the peculiarities of pharmaceutical marketing strategies of the multinational research based companies to the consumer, still do not stock the parallel imported version.

Drug Dosage: Another means to prevent imports is for companies to apply for product licences for a formulation in, for example, 10mg strength in Spain but 20mg in Germany. The patient in Germany, the country of import, will have to take two tablets of the Spanish version as against one of the domestic preparation-this creates customer resistance. This practice will be curtailed as centralised approval becomes the normal route to obtain the required marketing authorisations for new or modified New Chemical Entities (NECs) resulting in a single licence valid throughout the EU.

Pack Sizes: There are, of course, cultural as well as prescribing differences throughout member states. These will take more than one generation to eliminate if indeed it ever happens. Once again, the United Kingdom is at variance with other European countries in that traditionally, pack sizes in this country have been in multiples of seven whereas on the continent, the norm is in multiples of five or 10. The EC are discussing pack size harmonisation although the innovative industry is lobbying against this despite the obvious cost savings the measure would bring in its wake. We anticipate this will happen in the medium term.

Litigation: Ever since the inception of the parallel trade in pharmaceuticals, members of the research based industry have litigated against the small parallel importer who they claim is a threat to their very existence. They have expended millions of dollars, countless man hours and generated reams of paper at the expense of the environment to little effect.

They attempt to justify this wasteful expenditure of resource on the unsubstantiated grounds that the parallel trade places their research programmes at risk. A cynic might feel that a reallocation of this resource into research might yield a more significant benefit or return in terms of public health. The industry, however, in an attempt to protect the high margins it enjoys in many of the major world economies, contends that the advantages of litigating outweigh the obvious and costly disadvantages: why, because the very process of going to court offers significant benefits:

- During the action, an injunction may be obtained preventing the importer from dealing in the subject product; by the time the case is determined the window of opportunity may have passed;
— The cost of defending an action may be unsustainable by the small parallel importer unless he can do so through his industry association.

For the record, in Annex 3[2] we list the significant cases which have been brought by one or another member of the innovative industry against one or another member of PPDI: all have been determined in favour of PPDI.

3. THE PRESENT SCENARIO

Notwithstanding the confrontational attitude and approach adopted by the research based industry, a trade which started as a small entrepreneurial activity from the back of a few pharmacies has grown into a mature industry employing several thousand people operating throughout the European Union.

Despite continued and repeated overtures from the PPDI, there are few signs of any change of direction in policy or attitude by the innovative companies towards the parallel importer. The occasional smaller multinational may send out a positive signal but the larger companies appear determined to try to curtail the growth of the PPDI as much as they can. Further legal cases appear inevitable. These will simply sustain the income of lawyers and do nothing for either the promotion of public health or the quality of life for the citizens of the EU.

It is therefore against this background that we turn now to address the specific questions outlined in the brief issued by the Trade and Industry Committee.

It will of course be appreciated that our responses to the questions relate only to the pharmaceutical industry from the perspective of the API.

4. RESPONSES TO THE NOMINATED QUESTIONS

4.1 Why does "grey" and parallel trading occur?

The reason parallel trade occurs in the pharmaceutical sector is simply that this market is not subject to the principles of free pricing and competition is limited. In most member states within the EU, pharmaceutical prices are determined by Governments, increasingly through a system of reference pricing, in an effort to contain the ever increasing cost of medication to the public purse as a consequence of improved medical care and an aging population.

In general terms, identical medicines are priced cheaper the further south you travel within the EU member states. Thus the cheapest countries in ascending order are Portugal, Spain, Greece and Italy. These are closely followed by France and Belgium. The average price graph would then show a measurable gap before Austria, Finland and the United Kingdom.

In descending order from the member state where drug prices tend to be the highest, we have Denmark, Germany, the Netherlands, Sweden, and perhaps surprisingly, Ireland.

Although the total value of the PPDI trade expressed in absolute terms is the highest in the United Kingdom, when expressed the values as a percentage of the relevant national drug bill, the country which benefits the most remains the Netherlands. It is important to bear in mind that the United Kingdom is one of the major sources of supply for parallel exports of medicinal products: the exact figure is not readily quantifiable but it is thought to be greater than the value of the imported parallel trade. This fact is seldom acknowledged by the research based industry.

Parallel trading in pharmaceuticals is simply the means by which market forces respond to the different prices of identical products in EU member states.

4.2 Costs and benefits accruing to the producers and to the consumers

The principal customer in the United Kingdom is the UK Government. The Government benefits in two principal ways as a consequence of the existence of a healthy PPDI in this country:

1. Through the "claw-back". It is estimated that this mechanism yields a saving of some 2 per cent of the total drug bill to the Treasury each year.
2. Perhaps more importantly but unfortunately unquantifiable, the PPDI acts through the addition of a competitive element into the marketplace. There is no doubt that the existence of the parallel imported product helps to contain the price of specific drugs: there are many examples of both where the original manufacturer has been unable to seek a price increase and where prices have been reduced as a direct consequence of the share of the total market being obtained by the imported version. In addition, increasingly there is evidence of the multinational company offering the import quantities of the domestic product at or near the cost of the imported version: effectively this is a price reduction which feeds back into the system. (Mention has

already been made of the bulk discounts offered to hospitals and other large buying groups on selected products by the original manufacturers.)

The Research based industry claims that the financial impact of the parallel trade in pharmaceuticals "costs" it several million pounds per year. This claim has never been really substantiated and has certainly never been produced in the public domain for open discussion: the best we have seen to date has been the occasional study funded by the research based industry and undertaken by economic analysis firms which purport to quantify the revenue loss sustained by individual companies.

The research based industry overestimates the volume and value of the trade using unreliable data from sources which admit that the figures used are, at best, extrapolated estimates. To our knowledge, no major multinational pharmaceutical company has ever quantified the reduction in its research & development (R&D) as a direct consequence of the parallel trade in its products. Also, to our knowledge no major pharmaceutical company has ever explained why it has chosen to locate a significant proportion of its manufacturing capacity in low cost countries, for example Ireland and Spain, other than because of its desire to contain its manufacturing costs. When, for instance, Boots was in the industry sector, some of its product portfolio was only manufactured in Spain simply because at the time that was a more cost effective location and by using the benefits of an intra-group transfer pricing mechanism, margins were maximised despite the pricing regimen subsisting in that country for the domestic product.

4.3 Where does the public interest lie in respect of such trading?

For many years now, consumer groups throughout northern Europe have been supportive of the PPDI. The API has been championed by, for example, Consumers in the European Community Group (CECG) which is the umbrella body for some 31 professional and voluntary organisations in the United Kingdom which have an interest in the effect of EU policies on UK consumers. Similarly, the Association has been supported by both BEUC and COGACE. The Association has made presentations to Intergroupe pour la politique des consommateurs whose president at the time was Pauline Green MEP.

These groups recognise the positive role played by the PPDI in the cost containment programme of the NHS in the United Kingdom and the appropriate sister bodies in other member states.

Given the special and peculiar characteristics of the pharmaceutical market place as outlined in the previous sections of this submission, consumer groups have recognised the valuable pressure points applied by the PPDI. Price differentials vary upwards from some 10 per cent and are on average some 20 per cent of the UK drug tariff price, a not insignificant contribution towards the costs saving elements within the supply chain.

4.4 Should more or less protection be given to brands and are trade marks insufficiently or excessively protected?

Brands and/or trade marks are presently afforded adequate protection as far as their application in the pharmaceutical industry is concerned. Given that consumer choice is exercised by a person two steps removed from the ultimate consumer whilst the pharmacist chooses exactly what to supply, it is arguable that brand names are almost an irrelevance. Industry observers have noted however, that the generic or chemical names of drugs are often unpronounceable for even the trained professional, hence the use of brand names.

The recent Silhouette decision by the ECJ provides for the strengthening of trade mark rights [1998] CEC 676; [1998] FSR 729. The Judgement indicated that Article 7(1) of the Trade Mark directive did not provide for the international exhaustion of rights and, more significantly, did not leave it open for national courts to provide for international exhaustion of rights.

It would appear that the doctrine of exhaustion of rights as applied to IP rights is limited to the EEA alone. The IP rights, therefore, remain protected if the product is marketed without consent outside the EEA. Given this effective monopoly, it is difficult to see a justifiable case for any further extension of rights.

4.5 What are the main problems with existing measures to detect and prevent counterfeiting and piracy? How can such measures be made more effective? Are there problems with definitions?

The Medicines Control Agency, the UK regulatory authority, is on public record that counterfeiting and piracy within the pharmaceutical sector is not an issue. As a direct consequence of the standards which are followed by all parts of the pharmaceutical industry (manufacturers, importers, distributors, wholesalers, pharmacies and dispensing doctors plus the various regulatory and professional bodies), all of whom maintain a watching brief to ensure compliance with the regulations governing the storage, distribution and dispensing of medicinal products for human consumption, cases of counterfeit product entering the UK supply chain are almost unknown.

The quality assurance programmes which are in place ensure that the highest possible standards are maintained. Public confidence in the quality of medications available on the market appears to remain consistently high and justifiably so.

There is an arguable case for pressure being brought to bear upon the manufacturers to ensure that, within the bounds of commercial reasonableness, supply was always marginally in excess of demand thereby reducing, if not eliminating, the appeal of counterfeit product. Secondly, the industry, in the event of a counterfeit product being detected, should be legally obliged to make the findings of the mandatory subsequent investigation available, thereby facilitating open and transparent debate. There can be no legitimate foundation for maintaining a shroud of secrecy in such circumstances.

4.6 How can IP rights be more effectively agreed and enforced internationally?

There is little evidence to support any view that within the United Kingdom IP rights need to be tightened or enhanced. There is likewise no requirement within the EU—indeed it is to the contrary. As this submission has noted, the pharmaceutical sector has repeatedly used its IP rights to attempt to prevent the operation of the cardinal tenet of the common market, the free movement of goods. The position that may exist outside the EU is beyond the competence of the API to address in this submission as the scope of our activity is presently restricted to trading within the member states of the European Union.

5. CONCLUSION

The Communication issued by the Commission immediately before the Third Bangemann Round Table Conference in Paris in December 1998 entitled a "Single Market in Pharmaceuticals" Com (98) 588 recognised the importance of the parallel trade in pharmaceuticals. It states that the PPDI is an important "driving force for market integration where there are significant differences in prices and consequently, for achieving the single market."

There appears to be a growing consensus that the remaining price restrictions should be lifted in the non-prescription (OTC) product area as well as the out-of-patent product area. This would increase competition, allowing prices to converge with the market becoming effectively integrated. However, it would appear that market integration is a long way off so far as the in-patent product sector is concerned. The innovative industry is determined to maintain the healthy profit ratios it enjoys in the northern European countries. With governments unlikely to relinquish control of pharmaceutical pricing, and with generic substitution resisted by vested interests, the future of the parallel trader would appear strong, allowing the benefits flowing from the existence of the PPDI to continue to support drug cost containment objectives.



TUESDAY 18 MAY 1999

HOUSE OF COMMONS

SELECT COMMITTEE ON TRADE AND INDUSTRY

TESTIMONY OF MS PHILIPPA CLARE, RISHWORTH CHASE TRADE CONSULTANCY

Chairman

545. Good morning, Ms Clare. We have invited you today because you are one of the self-confessed parallel traders. I do not mean that in a derogatory sense and do not necessarily mean parallel trading requires self-confessing, but you certainly assist the business of parallel trading, from what we can understand. You trace parallel goods back through the supply chain to check their authenticity. While we accept that individual cases might be confidential, can you outline how you would go about your job? How would you track these goods back and find out where they came from?

(Ms Clare) It is actually very simple. The request, actually, for this service came from parallel traders themselves who wanted to extricate themselves from the possibility of selling counterfeit goods. Parallel trading/counterfeit should not be completely inter-twined. The main problem from all traders' points of view, once goods have gone into the wholesale chain, is there is a great need for each of them to observe the confidentiality back down the line, because everybody is worried about being hooked out of some level of profit. Our job is to, basically, begin with the goods at this end and find out where they originated from at that end, putting all the links in the chain inbetween, while guaranteeing confidentiality to each link of the chain so that we do not inform party A who party C is, etc, and so that confidentiality of that supply chain is maintained. There are two paper trails: one is the trail of money, the invoice trail, which if at all possible, particularly with large consignments, will link up with actual transactions, if the wire transfer has been made or whatever. The other line is the physical movement of the goods so that if they are believed, for example, to have originated within the European Union we should be able to get some level of freighting bill from whoever transported them to show that they actually did come originally from the distributor or an authorised wholesaler or an authorised shop. We will also do checks on each section of the chain to ensure that companies actually exist, that they are where they say they are and that they actually know they are involved in that transaction. As far as possible we check that the original paperwork, from the brand holder themselves is unsanitised, that is, not blacked out at all. We can check that it should be authentic. That is really the trailing that is done.

546. You do not actually authenticate branded goods, your evidence suggested, but do you find brand owners happy to authenticate the goods? Are brand owners willing to assist in this?

(Ms Clare) Some are, because they see our service actually as a very good buffer state between them and counterfeiters. They know that parallel traders exist and, in a sense, we are almost an internal police service. So there are brands who are extremely helpful, and they are brands who are not helpful at all. Basically, I would prefer to be able to send samples back to all of the brands before goods go into the retail chain, because paperwork on its own is only half the story—the goods themselves are the other. The other thing we try very hard to do, although this is difficult, is to ensure goods are not mixed, that the quantities remain as consistent as possible, that the transactions are as consecutive as possible, because mixing does happen. In that way parallel goods can be a way of transporting counterfeit.

547. What about the issue of consent, because that is, obviously, quite central to the acceptance of the goods? How do you interpret a brand owner having given consent? Is there some means whereby you can do that easily? How do brand owners react when you start asking them about matters of consent, which seem to be central to the permission issue?

(Ms Clare) As far as consent goes, if you can trace a transaction to its origin you can actually find out how that transaction was conducted: who said what, where, when; if there were any letters attached to the transaction; if there was any express prohibition put on the movement of goods at that particular moment in time. In one or two large consignments—I cannot remember exactly the quantity—there was about £12 million worth of Calvin Klein underwear sold directly from Warner Co in the States to a parallel trader in Denmark, and that was associated with a whole sheaf of letters from the relevant vice-president of Warner Co. We ensured that everything was countersigned, and there were no forgeries, as far as we possibly could, and that is a very simple case where written consent for the resale of those goods in the European Union was given. Again, this is anecdotal, but I know of instances where large consignments of well-known brands are sold in the States with a representative of the brand holder—be it the marketing director or the export manager, or whoever it is—present at the meeting who simply says nothing but knows perfectly well that those goods are coming into the European Union. I think, certainly in the garment industry anyway, the *Silhouette* ruling affected the importation of goods, particularly from America, (although I am not terribly sure why it was so specific) because a lot of the retailers who had moved into branded merchandise, larger retailers, suddenly

said "We are not taking anything from America. So that is it"—almost whether it has got consent or not. So the issue of consent is problematic. Generally speaking, I do not ask too many questions because if a tacit consent has been given and somebody is asked to make it explicit it might well be the case that his or her job would be on the line if it all had to be made too open. Having said that, I do have quite a lot of documentation from brands, leading or otherwise, which have been entrusted to us in confidence and provided that I can send copies of them to you, again, in confidence, then I am perfectly happy to give those to you.

Chairman: We often receive things in confidence. That would be helpful and we would, obviously, consult with you before we alluded to them in our report. We would be grateful for that.

Mr Berry

548. I get the impression that brand owners frequently supply the parallel market when it is in their own interests and they take legal action when it is not—and there is a perfectly rational economic case for behaving in that way. Is that what goes on? (Ms Clare) Certainly the supply of goods is definitely within the brand holder's control. Indeed, much of the counterfeiting alluded to earlier could actually be stopped by the brand holders themselves—certainly in the garment industry—if they had more control over their own factories and the amount of information that was given to each factory. Also, if they had more consistent styling for their garments, so they actually knew which garments were on the market worldwide. A lot of them do not because each sector is carved up. On the issue of putting goods into the parallel market, the Calvin Klein underwear is a case in point. Immediately before the *Silhouette* ruling there were a lot of genuine American Calvin Klein jeans. At the time they were intended to go into the Far Eastern market, the Far Eastern market dried up and they had to put them somewhere, and the parallel market going out into Europe was certainly one of the places where they were intended for. Then the *Silhouette* ruling happened and they were stuck with a lot of stock. There is a lot of stock.

549. In your written submission you talk about "parallel trade is also a great sponge for over-production", and that brand owners in one country will often offload surplus production in another part of the world to retain value in its home market. Again, that is an absolutely rational point of view, although there is this curious denial that this activity could take place. Are you able to give us more examples of where this might occur—either now or in written evidence subsequently?

(Ms Clare) I can give you a wider answer in written evidence, but if you look at the European situation and turn the whole thing on its head, the *Silhouette* ruling has permitted European brands to gather together all their excess stock and ship it out. I know—and have contact with—a lot of American traders stock houses and so on, who are getting container loads of Armani jeans, container loads of Prada bags and sunglasses galore, and are calling us up on a regular basis saying "Why can we not bring this back into the European Union? It is European stock, surely." "Well, no, because you are the first recipient of it and I think, if you look at your contract, there will be a prohibition on reselling to the European Union." They are dumping over in America, wholesale.

Mr Laxton

550. Have your company, or any of your clients, come across any problems associated with branded grey goods being totally different from those that would be retailed here in the United Kingdom? I think the example we got, a little while ago on the evidence, was Colegate toothpaste where a particular brand of Colegate toothpaste in South America was totally different from what you would purchase in this country, but the packaging was the same with the branded name.

(Ms Clare) It depends. I will concentrate, again, on the garment industry. The Nike and Sainsburys issue which was brought up earlier is part of this problem, if you like. The Nike distributor who sold those goods to the wholesaler—who then sold them on to Sainsburys, via one or two intermediaries—at the time of manufacture was under licence to Nike. (I should probably put "allegedly" in front of all this.) Anyway, the thing was that Nike at the time did not have sufficient control over Nike in the Philippines, and the garments they were manufacturing for the home market, although the quantities they were producing were absolutely enormous, were substantially different from American and, certainly, from European Nike products. You will find that this is the case with most branded clothing; that different designs are aimed at different markets. It does not mean that the goods are counterfeit, the licence will have been paid in that particular area, and the brand holder, or the trade mark holder, will have received its levy for its massive advertising budget etc, but they are significantly different. American Lacoste, for example, is very inferior to European Lacoste. American Lacoste is actually aimed at a completely different market to European Lacoste; it is, sort of, not quite £2 a T-shirt but along those lines. It is a low-grade brand. Yves St Laurent in America have the most incredible designs. If you found them in a shop here and saw Yves St Laurent on the lapel you would think "There is something wrong", because they are incredible, they are just so garish and shocking. The point is that Yves St Laurent in France has no control over those designs. I do not think they have, anyway. If they have then they need their heads examining. A lot of the problem with policing goods on the counterfeit market is this fragmentation given through licence agreements and contracts between licensed distributors, and whether or not they are allowed to manufacture and whether or not they are allowed to create their own designs; how they utilise the logos and how they utilise the trade marks, etc. It is very difficult.

551. As you know, the United States have looked at this and they are starting to exercise some controls on grey or parallel imports that are substantially different, unless they are clearly labelled as such. Have you got any particular views on that? Or, perhaps, do you think it may be forcing brand owners to differentiate between products as a way of preventing grey importing, for example?

(Ms Clare) I am not entirely sure what you mean by "preventing grey importing". Taking Lacoste as an example, before the *Silhouette* ruling happened there was a very large consignment of legitimate American Lacoste which was available for sale in a large retailer. Lacoste took action against the retailer, not on the basis of whether the goods were legitimate or not but, actually, almost on a "passing off" issue; that Lacoste were passing themselves off as being Lacoste, and that by putting a label above them saying "Lacoste T-shirts" at whatever it was, and they were massively inferior, Lacoste Europe did not like it because their trademark was being used in a lookalike way. What I am saying is that that is almost an internal brand problem. I was reading an article the other day in Ireland about this issue and it was talking about the problem of Caterpillar heavy duty machinery in the States and the quantity of heavy duty machinery which was being shipped in from Mexico. The article was saying "If there is an accident on these inferior machines which are made for Mexico how are we, in America, going to cope with it?" My first feeling was "Why should Mexicans have things which are going to kill them and the Americans do not?" That does not seem to me an issue for parallel traders, that seems to me to be an issue for the brands and the policing of the brands and the consistency of their own quality.

552. We had some evidence, for example—and I forget what the actual product was—where quite clearly manufacturers were putting together a product (I think it was an alcoholic product but I cannot remember what it was) and the bottle was identical but the contents were not even, perhaps, subtly different but quite different for different markets around the world. The Japanese taste for a particular product being quite different from the European taste. Do you think we are likely to be seeing more of that?

(Ms Clare) I do not think there is going to be more, in that the targeting of particular markets has been going on for a very long time. Actually, parallel trade under an international exhaustion regime was continuing in the United Kingdom up to July 17 last year. As I said to the *Financial Times*, as far as Rishworth Chase is concerned, since July 17 the quantities of counterfeit goods which we have seen has increased beyond measure. I am stunned and staggered by the quantities which are entering the United Kingdom. It goes back to your question about whether, if legitimate goods were available, this would actually stamp out counterfeit. I personally think the answer is yes. Counterfeiting has expanded because of the desire for branded merchandise which has been fuelled by the large supermarkets and has been fuelled by these cost-cutting, out-of-town hypermarket places. They want goods. That is what they want, and they are presently being prevented from buying legitimate goods from outside the European Union. The quantity of European goods is very small. If you are going to break the law by selling goods a little bit by bringing legitimate goods in from outside, why not break the law completely and sell counterfeit goods at a lower price? Before the *Silhouette* ruling came in, that need was being supplied by genuine goods, which the brand holders were being paid their duty for and the licence was being paid. At the moment, I am beginning to feel that what Rishworth Chase is doing, increasingly, is not tracing back to ensure that goods are probably genuine, we are tracing back to find out where the counterfeit stuff is coming in, so that I can write round to people and say "Do not bother even tackling such-and-such a brand in such-and-such a way, that has come from such-and-such a place, because it is a waste of everybody's time."

Mr Butterfill

553. Brand owners, of course, say that if we had international exhaustion and parallel goods from outside the European economic area this would prevent them from innovating and cause them damage. Do you think that innovation, really, is genuinely likely to suffer if that were to happen?

(Ms Clare) Why should it? Why should a free movement of goods prevent innovation? If the brands wish to keep their competitive edge on a worldwide stage then I have not seen any increased innovation in the last twelve months from any of the brands. We have not suddenly had a jack-in-the-box effect and entirely new ways of producing toothpaste or razor blades, or anything else.

554. Your view would be that they would actually sell far more of the genuine product?

(Ms Clare) My view is very strongly, yes.

555. They would not have the consequences that *Silhouette* has produced, as far as you perceive it?

(Ms Clare) And it would open up more of a possibility of actually cutting off the routes for these counterfeit goods to be sold into. You have two ways of stopping it: you stop it at the manufacturing end or you stop it at the retail end. If the retailers are being told that they are selling counterfeit goods and they have no price incentive for doing so, they are much more likely to turn them away.

556. I can see that is an argument when we are talking about fashion goods, and particularly when we are talking about trainers or T-shirts, or whatever it happens to be. However, if we are talking about more sophisticated goods, like pharmaceuticals, where we have been given evidence that there is not a lot of counterfeiting coming into the United Kingdom (although there may be in certain third world countries) would your views still apply in those areas?

(Ms Clare) I think there are other regulatory bodies involved in things like pharmaceuticals and drugs which, because of the low percentage of any counterfeit coming into the United Kingdom or other parts of the European Union, seem to be doing their job very well. Again, I do not think there has been a marked increase or decrease in counterfeit drugs, etc.