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# The Impact of the Drug Export Amendments Act of 1986 on Foreign Tort Victims

James C. Grant

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## I. INTRODUCTION

In response to domestic pharmaceutical producers' demands, Congress amended the Federal Food, Drug, and Cosmetic Act (FFDCA) on November 14, 1986.[1] The advantages of foreign drug producers over United States drug producers prompted Congress to enact the Drug Export Amendments Act of 1986[2] (DEAA) which was designed to help United States drug producers compete effectively in the world market.[3] The DEAA now puts domestic producers on more of an equal basis with the rest of the market by allowing them to export unapproved drugs.

The first section of this Note will examine the new amendment and outline its requirements. Then, it will explore the product liability laws of New Zealand, Great Britain, and West Germany. This discussion will present a broad overview of the divergent product liability regimes employed by various countries. These sections will also serve as a warning to the careless domestic producer. Finally, this Note will critique the present statute and the resulting opportunities for abuse that arise from the language of the statute.

## II. DRUG EXPORT AMENDMENTS ACT OF 1986

### A. *Purpose of the Amendment*

An anomaly existed under the previous FFDCA.[4] The Act prohibited United States producers from exporting new drugs to many countries where the drugs had already been approved.[5] This prohibition caused a large imbalance of trade in the domestic pharmaceutical industry. By allowing exportation under the DEAA, Congress hopes to cure this problem.[6]

Another goal of the DEAA is to encourage producers to develop drugs

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1. 21 U.S.C. §§ 301-92 (1982 & Supp. IV 1986).

2. 21 U.S.C. § 382 (Supp. IV 1986).

3. S. REP. No. 225, 99th Cong., 2d Sess. 4 (1985), *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6298, 6301.

4. 21 U.S.C. § 301 (1982).

5. S. REP. No. 225, *supra* note 3, at 4, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6301. It is well-publicized that Food and Drug Administration (FDA) approval is much slower than foreign approval. A 1980 Government Accounting Office (GAO) survey indicated that over 70% of newly approved drugs were approved in foreign countries before they were approved in the United States. *Id.* at 5, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6302. This difference led to the loss of domestic jobs and revenue. *Id.* at 6, *reprinted in* 1986 U.S CODE CONG. & ADMIN. NEWS at 6303.

6. *Id.* at 10, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6306.

that can combat diseases which are found in underdeveloped countries but rarely in the United States.[7] Prior to the DEAA, these drugs were seldom admitted for domestic approval because the absence of a corresponding disease made production of the drugs unprofitable. The DEAA creates an incentive to aid these afflicted countries.[8] Finally, by imposing rigorous requirements for exportation, the Act prohibits the dumping of dangerous drugs.[9]

### B. *Analysis of 21 U.S.C. Section 382*

#### 1. The "Blanket" Prohibition

The first subsection of the DEAA imposes a blanket prohibition on the exportation of drugs.[10] The statute covers any drug or biological product that requires approval under the FFDCA or the Virus-Serum-Toxin Act.[11] The statute prohibits the exportation of any drug that is not currently approved, licensed, or exempt from the FFDCA, unless the new statute's requirements are fulfilled.[12] If the statute's requirements are not met, the drug is deemed adulterated and misbranded, and exportation of the drug is illegal.[13]

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7. *Id.* at 12, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6308.

8. *Id.* at 12, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6308. However, the drug company must actively seek domestic approval of the drug. *See infra* Part II, B, 2.

9. *See* 21 U.S.C. § 382 (Supp. IV 1986). The FDA has no mechanism to keep a country from reexporting.

10. 21 U.S.C. § 382(a) (Supp. IV 1986), which states:

> A drug (including a biological product) intended for human or animal use —
>
> (1) which —
>
> (A) requires approval by the Secretary under section 355 of this title or section 360b of this title, or
>
> (B) requires licensing by the Secretary under section 262 of title 42 or by the Secretary of Agriculture under . . . [21 U.S.C. 151 et seq.] . . ., before it may be introduced or delivered for introduction into interstate commerce to a country, and
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> (2) which does not have such approval or license, which is not exempt from such sections or Act, and which is introduced or delivered for introduction into interstate commerce to a country, is adulterated, misbranded, and in violation of such sections or act unless the export of the drug is authorized under subsection (b) of this section."

*Id.* § 382(a).

11. 21 U.S.C. §§ 151-58 (1982 & Supp. IV 1986).

12. 21 U.S.C. § 382(a)(2) (Supp. IV 1986).

13. *Id.*

### 2. Requirements for Exportation

There are only four types of products that may be exported under the DEAA: "new drug[s]," "biological products for human use," "biological product[s] for animal use," and "new animal drug[s]."[14] To obtain approval to export these products, a domestic producer must be "actively" seeking domestic approval under the appropriate statute.[15]

Congress also placed restrictions in the statute on the number of countries that may receive the drugs.[16] Congress intended to permit exportation only to countries with highly developed drug approval systems. By limiting the importing countries, Congress sought to avoid the dumping of hazardous drugs.[17] Not only must the country appear on a statutory list, but the country must already have approved the product and the

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14. *Id.* § 382(b)(1)(A). This section reads:

A drug (including a biological product) may, upon approval of an application submitted under paragraph (3), be exported if—
(A) the drug contains the same active ingredient as a—
(i) new drug—
(I) which has an exemption under section 355
(i) of this title, and
(II) for which approval is actively being pursued by the person who has the exemption,
(ii) biological product for human use—
(I) which has an exemption under section 355
(i) of this title, and
(II) for which licensing of the biological product under section 262 of title 42 is actively being pursued by the person who has the exemption,
(iii) biological product for animal use—
(I) for which authority has been granted under the Virus-Serum-Toxin Act [21 U.S.C. § 151 et seq.] for the preparation of an experimental drug product, and
(II) for which the licensing of the biological product under such Act is actively being pursued by the person who has the authority, or
(iv) new animal drug—
(I) which has an exemption under section 360b(j) of this title, and
(II) for which approval is actively being pursued by the person who has the exemption, . . .

This section cures the previous defect in the FFDCA. Under the Amendment, it is possible to export new unapproved drugs under certain circumstances.

15. *Id.* Each type of drug has its own corresponding approval process. *See supra* note 14.

16. 21 U.S.C. § 382(b)(4)(A) (Supp. IV 1986). These countries are Australia, Austria, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and The United Kingdom.

17. S. Rep. No. 225, *supra* note 3, at 12, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6308.

product must be available for sale in the country.[18]

There is an exception to the prohibition against exporting to a listed country that has not approved the drug. If a producer ships to a country which has not approved the drug and that country reexports the drugs to an approved country, exportation to the non-approving country is permitted.[19] This exception is justified on the ground that the drug will not be used in the conduit country and the ultimate receiver is approved. A country may be added to the statutory list if it has developed a sophisticated drug approval process[20] and if its drug industry maintains high levels of quality.[21]

A third requirement for exportation is that the products may not be disapproved in the United States under its appropriate statutes.[22] A company may export drugs only when they are either in the domestic approval process or actually have been approved. The fact that a foreign country has approved a drug bears no weight on the possibility of export if the drug has been disapproved in the United States by the Secretary of Health. Also, the drug must be "manufactured, processed, packaged, and held in conformity with current good manufacturing practice. . . ."[23] Moreover, various sections of the FFDCA prohibit the adulteration of drugs.[24]

The DEAA also requires shipping packages to have a specific label when exported.[25] The label must read: "This drug may be sold or offered for sale only in the following countries . . . ."[26] Every country which will receive the drug must be listed on the outside of the package.[27] Although there is no legislative history on this requirement, it seems that a possible purpose for the requirement may be to help enforce the rule that only specific countries may import these drugs.

Not only must the drug not have been disapproved by the Secretary of

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18. 21 U.S.C. § 382(b)(1)(B) (Supp. IV 1986).

19. *Id.* § 382(b)(2). A problem arises if the drug never leaves the conduit country. Some commentators claim that the FFDCA has no mechanism to police this problem. *See* S. REP. NO. 225, *supra* note 3, at 63-64, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6331-32.

20. 21 U.S.C. § 382(b)(4)(B) (Supp. IV 1986).

21. *Id.*

22. *Id.*§ 382(b)(1)(C). This section combined with section 382(b)(1)(A) are the heart of the DEAA. They conjunctively allow for the shipment of domestically unapproved drugs.

23. *Id.* § 382(b)(1)(D).

24. *See id.*

25. *Id.* § 382(b)(1)(E).

26. *Id.*

27. *Id.*

Health, but it also must not have been found to be contrary to the public health of the United States.[28] If the Secretary determines that domestic manufacturing of the drug poses a danger to the United States public health, it may not be shipped.

Next, the statute cross-references four subsections of the existing FFDCA that must be fulfilled.[29] First, the product must be in accordance with the specifications of the foreign purchasers.[30] Second, the exportation must not conflict with any of the laws of the importing country.[31] Third, the package must be labeled "intended for export."[32] Fourth, the drug must not be sold in the United States[33] if it is adulterated or misbranded.[34]

The final condition that must be fulfilled prior to exporting the drugs is that domestic approval must be "actively" sought during the exportation.[35] "Actively" is defined ambiguously so that it is incumbent upon the trier of fact to determine if the standard is met. The exporter must exercise a reasonable "degree of attention" and make a "continuous directed effort" to pursue the approval of the drug.[36]

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28. *Id.* § 382(b)(1)(F).
29. *Id.* § 382(b)(1)(G).
30. 21 U.S.C. § 381(d)(1)(A) (1982).
31. *Id.* § 381(d)(1)(B).
32. *Id.* § 381(d)(1)(C).
33. *Id.* § 381(d)(1)(D).
34. *Id.* § 381(d)(1)(D). This subsection appears to be superfluous. The first requirement that the product be in accord with the foreign countries' specifications should be taken care of by market influences. *Id.* § 381(d)(1)(A). A domestic producer will not ship where there is no demand for its products; and, it will only ship what foreigners wish to purchase.

The second requirement is met by section 382(b)(1)(B), which requires that the drug be approved in the import country. 21 U.S.C. 382(b)(1)(B) (Supp. IV 1986). One can assume that if the drug is approved, it will not conflict with the laws of the import country. Moreover, this second labeling requirement is redundant. Section 382(b)(1)(E) already requires a label. *Id.* § 382(b)(1)(E).

The fourth requirement prohibits the sale of the drug in domestic commerce. The DEAA allows exportation of unapproved drugs. If the drug is unapproved, it can never be offered for sale in domestic commerce notwithstanding the DEAA. Finally, the drug cannot be misbranded or adulterated. The blanket prohibition fulfills this requirement. *Id.* § 382(a).

35. *See* 21 U.S.C. § 382 (Supp. IV 1986).
36. The statute reads in part:

> The Secretary shall determine that an applicant is actively pursuing the approval or licensing of a drug if the applicant has demonstrated that degree of attention and continuous directed effort as may reasonably be expected from, and are ordinarily exercised by, a person before approval or licensing of a drug, such as the preparation for and the conduct of preclinical or clinical investigations, the analy-

### 3. Application Requirements

An application for export is required of any entity that desires to ship drugs abroad. The application must be submitted ninety days before the proposed shipment date.[37] The application is both informational and representational. It must set forth the proposed drug and the country and persons who will receive the drug.[38] The exporter must identify the producers of the drug[39] and it must indicate the origin of the exemption or authority under which the drug is to be exported.[40]

In addition to this factual information, an applicant must also make certain representations. First, the statute requires a certification that the exporter will ship only to enumerated countries and only in amounts that may reasonably be sold.[41] An applicant may ship to a conduit country only if it is shipping there solely for purposes of reexportation.[42] Second, the exporter must certify that the drug is approved in the foreign country and has not been withdrawn from sale.[43] Third, the exporter must represent that it has met all of the requirements for exportation.[44] Fourth, the domestic producer must certify that it is taking active measures to obtain domestic approval of the drug.[45] Finally, a written agreement from each receiving country, stating that no reexportation to an unapproved country will occur, must be produced by the applicant.[46]

Once an application is submitted, the Secretary of Health has thirty days to review it.[47] If all the necessary information and certifications have been submitted, the Secretary will conditionally approve the appli-

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sis of the results of such investigations, conferences on such investigations with government officials, and the preparation of an application of approval or licensing for the drug.

*Id.* § 382(b)(1).

37. *Id.* § 382(b)(3)(A).

38. *Id.* § 382(b)(3)(B)(i)-(ii).

39. *Id.* § 382(b)(3)(B)(vi).

40. *Id.* § 382(b)(3)(B)(v).

41. *Id.* § 382(b)(3)(B)(iii)(I).

42. *Id.* This exception is one of the serious flaws in the statute. One of the major safeguards imposed by Congress was to require that the drug be approved in the foreign country. The FDA has no mechanism to prevent the drugs from remaining in the conduit country that has not approved the drugs. This lack of enforcement ability undermines the safeguards in the statutory scheme.

43. *Id.* § 382(b)(3)(B)(iii)(II).

44. *Id.*§ 382(b)(3)(B)(iii)(III)-(V); *see supra* notes 14-36 and accompanying text.

45. 21 U.S.C. § 382(b)(3)(B)(iv) (Supp. IV 1986).

46. *Id.* § 382(b)(3)(B)(vii).

47. *Id.* § 382(b)(3)(C)(i).

cation.[48] If the certification concerning foreign approval of the drug is in order, the application will automatically be approved within five days of the conditional approval.[49]

### 4. Reporting Requirements

The statute imposes four main reporting requirements on domestic producers. A producer must notify the Secretary within fifteen days if any of the following events occur: a receiving country has withdrawn approval of the drug; a receiving country has withdrawn the drug from sale; or, a producer has withdrawn the drug from the domestic approval process.[50] In addition, domestic producers must notify the Secretary within fifteen days of the receipt of any information that reexportation is occurring.[51] Finally, the statute requires exporters to file an annual report with the Secretary of Health.[52]

The producer must cease exportation of the drug if the receiving country withdraws the approval of the drug or if the drug is withdrawn from sale or if a domestic producer withdraws its application for domestic approval, or if the domestic approval application is denied.[53]

### 5. Tropical Disease Allowance

The DEAA specifically permits the exportation of a drug produced to combat a tropical disease.[54] Requirements similar to those discussed in the preceding sections are imposed. Additionally, the Secretary must find that the drug is safe and effective for treating a tropical disease.[55] This determination must be based on "credible scientific evidence" and

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48. *Id.*

49. *Id.* An applicant may amend its application if it later decides to export to an additional approved country. This amendment should be submitted thirty days prior to the anticipated shipment date. *Id.* § 382(b)(3)(D).

50. *Id.* § 382(c)(1)(A)-(C).

51. *Id.* § 382(c)(1)(D).

52. *Id.* § 382(c)(2). The section provides:

> The holder of an approved application under subsection (b) of this section authorizing the export of a drug shall report annually to the Secretary after the date of the approval of the application of the actions taken by the holder in pursuit of the approval of such drug during the year reported on. Not later than 90 days from the date of the receipt of a report under this paragraph the Secretary shall determine if the holder is actively pursuing the approval of such drug.

*Id.*

53. *Id.* § 382(d).

54. *Id.* § 382(f).

55. *Id.* § 382(f)(1)(A).

"clinical investigations."[56]

To ship a drug produced to combat a tropical disease, the producers must again obtain the permission of the Secretary. In addition to the requirements discussed above, the applicant must demonstrate the manner in which the drug will combat the tropical disease.[57]

The reporting requirements for the tropical disease drug application are less burdensome than those for the regular export application. The producer has two requirements. It must report the receipt of any information concerning the existence of reexportation,[58] and it must report any adverse reaction the drug may cause.[59]

The statute contains enforcement mechanisms specific to the tropical disease drug allowance. If the drug fails to meet all conditions for exportation or if the producer fails to meet its reporting requirements or if the manufacture of the drug poses a threat to the public health of the United States, the Secretary will provide the exporter with notice of the defect.[60] The holder of an approved application has thirty days to correct such defects.[61] Other changes in circumstance will result in an immediate prohibition. If reexportation of the drug to an unapproved country occurs and this exportation poses an "imminent hazard to the public health," exportation is immediately prohibited.[62] An immediate prohibition will also occur if an exporter ships to a country that does not meet all the conditions precedent for receiving a drug and the drug is determined to be an "imminent hazard to the public health."[63]

### 6. Enforcement Mechanisms

The enforcement mechanisms of subsection (e) apply to nontropical disease drug exportation. Again, the Secretary has the power to prohibit exportation either immediately or after a defect has gone uncorrected for

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56. *Id.*

57. *Id.* § 382(f)(2)(E); *see also supra* notes 37-49 and accompanying text.

58. 21 U.S.C. § 382(f)(3)(A) (Supp. IV 1986).

59. *Id.* § 382(f)(3)(B).

60. *Id.* § 382(f)(4)(A)(i)-(iii).

61. *Id.* § 382(f)(4)(A). The statute also directs that the Secretary give the producer a written notice showing the reasons for prohibition. If the producer requests, it will be provided with the opportunity for an informal hearing. *Id.*

62. *Id.* § 382(f)(4)(B).

63. *Id.* § 382(f)(4)(C). In the immediate prohibition area, the holder of the application will be given the opportunity for a speedy hearing. The need for a quick hearing is bolstered by the fact that the Secretary's determination may not be stayed during the appellate process. Thus, to avoid potential economic harm to a shipper, a quick hearing is necessary. *Id.*

a specific time period. In a number of circumstances, an exporter has thirty days to correct a defect or exportation must cease.[64] One such defect is if a producer attempts to export outside the four categories of products.[65] Additionally, exportation may be prohibited if the drug is adulterated or if it is not manufactured in conformity with good manufacturing practice.[66]

The exported package must continue to bear the statutory label[67] and meet other conditions precedent to approval of export.[68] If an exporter is using a reexportation scheme, all of the drugs must leave the conduit country.[69] The domestic manufacture of the drug must not be contrary to the public health of the United States.[70] A producer is given a sixty day grace period if it is found not to be actively pursuing domestic approval of the drug. If the producer does not rectify the situation during this period, shipment must cease.[71]

There are two situations in which an immediate prohibition will result. The first arises when an importer reexports to an unapproved country;[72] the second, when a drug is exported directly to an unapproved country.[73]

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64. *Id.* § 382(e)(1).

65. *Id.* § 382(e)(1)(A); *see supra* notes 14-17 and accompanying text.

66. 21 U.S.C. § 382(e)(1)(A) (Supp. IV 1986); *see supra* notes 23-24 and accompanying text.

67. 21 U.S.C. § 382(e)(1)(A) (Supp. IV 1986); *see supra* notes 25-27 and accompanying text.

68. 21 U.S.C. § 382(e)(1)(A) (Supp. IV 1986); *see supra* note 29 and accompanying text.

69. 21 U.S.C. § 382(b)(2).

70. *Id.* § 382(e)(1)(B).

71. *Id.* § 382(e)(2).

72. *Id.* § 382(e)(3).

73. *Id.* § 382(e)(4). This part of statute appears to be anomolous, for subsection (6) reads:

> If the Secretary receives *credible evidence* that an importer is exporting a drug to a country which is not listed under subsection (b)(4) of this section, the Secretary shall notify the holder of the application authorizing the export of such drug of such evidence and shall require the holder to investigate the export by such importer and to report to the Secretary within 14 days of the receipt of such notice the findings of the holder. If the Secretary determines that the importer has exported a drug to such a country, the Secretary shall prohibit such holder from exporting such drug to the importer unless the Secretary determines that the export by the importer was unintentional.

*Id.* § 382(c)(6) (emphasis added).

The Secretary does not immediately act upon the receipt of credible information but rather must make a determination that the importer exported a drug to an unapproved

### C. *Criticism*

One major flaw of the DEAA is the lack of control the FDA has over the drugs once they are exported. Problems may arise if approved countries reexport drugs obtained under the DEAA to Third World countries. The statute does not provide for enforcement mechanisms to prevent such shipments.[74] In fact, France, Great Britian and Germany allow exportation of unapproved drugs to Third World countries.[75]

Officials from the FDA admit they have no actual power to enforce the restrictions on reexportation imposed by the DEAA: "I think that [it] would be very difficult [to enforce the restrictions]. . . . Transshipment would be the responsibility of the country to which the first shipment is made. . . ."[76] FDA officials also stated: "[O]nce the exportation is made and the product is in the foreign country you lose your ability to make the requirement stick and you lose your ability to police."[77] The result is that countries may receive drugs despite a prohibition by Congress.

Another criticism concerns the Tropical Disease Section of the Act.[78] The fact that the Act provides no guidance as to the definition of a "tropical disease" may allow drug producers to ship unapproved drugs that have no relation to the cure of tropical diseases. A definite standard must be formulated in order to guide drug exporters as well as law enforcement officials. Moreover, the Tropical Disease Section may not be utilized at all because many American producers have no interest in developing such drugs because they are unprofitable.[79] Many tropical diseases are found only in poor Third World countries that cannot afford to pay for costly drugs.

A final criticism may be made with regard to the "imminent hazard" standard in the enforcement provisions.[80] First, the provision only oper-

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country. Thus there is a delay of time between the receipt of credible evidence and the "immediate" prohibition. Moreover, the statute allows a wide exception for unintentional reexportation. This exception undercuts the rigid prohibition of export to unapproved countries contained elsewhere in the statute. *See id.* § 382(e)(4).

74. *See id.* § 382.

75. *See* S. REP. NO. 225, *supra* note 3, at 63, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6331 (minority views of Sen. Howard Metzenbaum).

76. *Id.* at 63, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6331 (minority views of Sen. Howard Metzenbaum).

77. *Id.* at 63, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6331.

78. *See* 21 U.S.C. § 382(f) (Supp. IV. 1986).

79. S. REP. NO. 225, *supra* note 3, at 59, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6327.

80. *Id.* at 65, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6333. Export of drugs must cease if they pose an imminent hazard to the public health. 21 U.S.C.

ates after the damage has occurred. Second, the standard has been found to have been met domestically only once in twenty years.[81] Yet, since 1971, over 7,000 drugs have been recalled.[82]

It is with this statutory scheme and these criticisms in mind that this Note will examine the product liability laws of the three countries. Issues that are important in examining these laws include: whether a foreign consumer will have proper redress if harm results from a drug; whether that redress will be available in the consumer's country or the United States; and whether foreign laws adequately compensate these victims.

## III. FOREIGN PRODUCT LIABILITY LAWS

The product liability laws of many other countries differ greatly from those of the United States. There have been movements among countries to make their laws uniform; true uniformity, however, has yet to be achieved.[83] This section will analyze the product liability laws of New Zealand, Great Britain and West Germany. These countries illustrate several points on a continuum. First, New Zealand has a regime in which damages are not available for tort victims.[84] Thus, a drug producer will bear no liability in New Zealand for injuries caused by its products. The law of Great Britain permits negligence and breach of warranty actions against drug producers for injuries caused by their products.[85] In contrast, West Germany statutorily imposes strict liability on producers of defective pharmaceutical products.[86]

### A. *New Zealand*

#### 1. Background

In the late 1960s New Zealand grappled with the defects of its common-law tort cause of action. Many believed that their current tort system was not achieving its dual goals of compensation and deterrence.[87]

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§ 382(e)(3)(A)(iii) (Supp. IV 1986).

81. S. REP. No. 225, *supra* note 3, at 59, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6333.

82. *Id.* at 59, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6333.

83. *See infra* notes 174-90 and accompanying text.

84. *See infra* notes 87-146 and accompanying text.

85. *See infra* notes 147-68 and accompanying text.

86. *See infra* notes 191-230 and accompanying text.

87. *See* G. PALMER, COMPENSATION FOR INCAPACITY 23-24 (1979); *see also* Brown, *Deterrence in Tort and No-Fault: The New Zealand Experience*, 73 CALIF. L. REV. 976 (1985).

The problem of the uncompensated victim was of great concern in New Zealand.[88] Tort victims were not compensated for their injuries unless they could prove fault. Statistics revealed that a large percentage of injured people received no compensation.[89] Moreover, when victims were compensated, much of their award did not reach them. Legal fees and administrative costs consumed a large portion of the tort plaintiff's recovery.[90] Another problem with the tort system was the delay in receiving payment.[91] Despite an injured party's urgent need for funds, maintaining a cause of action for negligence often took years.

Finally, a major goal of tort law—deterrence—was not truly being promoted.[92] The fact that many tortfeasors had third party insurance greatly undermined the ability of the tort system to deter injurious actions. The ineffectiveness of criminal sanctions against tortfeasors also hindered the deterrent effect of the tort system.[93]

These flaws led the government of New Zealand to appoint a commission to investigate and recommend a new system of compensating victims of injury.[94] This commission, chaired by Mr. Justice Woodhouse, issued the revolutionary Woodhouse Report that held: "[W]hatever the cause of incapacity and wherever it might occur, society must no longer tolerate the grudging and artificial discriminations that until now have blemished the distribution of public moneys supplied by the community at large."[95]

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88. *See* G. PALMER, *supra* note 87, at 23.

89. *Id.* Surveys from several countries including the United States and Great Britain, revealed that only 13% to 63% of victims were compensated for various injuries. *Id.* Obviously, these figures indicate that a large group of people received no aid.

90. *Id.* at 23-24.

91. *Id.* at 24. The New Zealand report often relied on statistics from the United States. Palmer cited a United States Department of Transportation study that found that average delay in recovery was roughly four years. *Id.*

92. G. PALMER, *supra* note 87, at 24, 35. Many argued that the abolition of tort liability would lead to a rise in careless activity. Professor Brown refuted this argument. Brown, *supra* note 87, at 1001. Professor Brown compared motor accident rates and motor litigation rates before and after New Zealand introduced its accident compensation scheme. He hypothesized that if the tort law deterrent effect was lost by implementing a social insurance scheme, both accidents and utilization should increase. He found that utilization did increase. This increase, however, was so gradual that it was more likely related to a wealth effect than the abolition of tort liability. *Id.* at 985. Moreover, the accident rate declined steadily after the adoption of the Accident Compensation Act. *Id.* at 986-90. Thus, deterrence of accidents did not decline under New Zealand's social insurance scheme.

93. G. PALMER, *supra* note 87, at 35.

94. *See* T. ISON, ACCIDENT COMPENSATION 13 (1980).

95. G. PALMER, *supra* note 87, at 290. Palmer quotes the Report of the National Comm. of Inquiry, Compensation and Rehabilitation in Australia, para. 225 (1974). A

The report was eventually enacted as the Accident Compensation Act in 1972.[96]

### 2. Coverage

The purpose of the Accident Compensation Act is to compensate[97] "all persons who suffer personal injury by accident in New Zealand."[98] The Woodhouse Report set forth the philosophy of this all-encompassing coverage. The report stated that "the general basis of protection should be bodily injury by accident which is undesigned and unexpected so far as the person injured is concerned. . . ."[99] Accident is not defined in the Act but is used in its ordinary sense.[100] The Act provides twenty-four hour coverage, and coverage does not depend on cause or fault.[101]

Injury by defective drugs appears to come within the definition of "personal injury by accident":

> Personal injury by accident — (a) includes—
> (i) The physical and mental consequences of any such injury or of the accident:
> (ii) medical . . . misadventure. . . .
> (b) Except as provided in the last preceding paragraphs [personal injury by accident], does not include—. . . .
> (ii) Damage to the body or mind caused exclusively by disease, infection, or the ageing process."[102]

Thus, personal injuries caused by drugs appear to be covered by the Act.[103]

Not only does a facial reading of the Accident Compensation Act appear to cover injury from defective drugs, but the statute is also intended to cover disastrous responses to medical treatment.[104] A major commentator on New Zealand law stated that an "extraordinary drug reaction

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similar statement appears in the report of the Royal Comm. of Inquiry, Compensation for Personal Injury in New Zealand, para. 57 (1967) [hereinafter Woodhouse Report].

96. Accident compensation Act 1972, 1 N.Z. Stat. 521, *as amended by* 3 N.Z. Stat. 1552 (1982).

97. 3 N.Z. Stat. § 26 (1982).

98. *Id.* § 27(1).

99. G. PALMER, *supra* note 87, at 245 (quoting Woodhouse Report, *supra* note 95, at para. 289).

100. *Id.* at 246.

101. T. ISON, *supra* note 94, at 18.

102. 3 N.Z. Stat. § 2 (1982).

103. Palmer, *Accident Compensation in New Zealand: The First Two Years*, 25 AM. J. COMP. L. 1, 38-39 (1977); *see also* G. PALMER, *supra* note 87, at 255.

104. G. PALMER, *supra* note 87, at 255.

far beyond the ordinary hazards of the treatment" would be covered.[105] A review decision further defined medical misadventure as when "a person suffers bodily or mental injury or damage in the course of, and as part of, the administering to that person of medical aid, care and attention. . . ."[106]

There is one exception to the all-inclusive coverage of the Act. If a claim for damages lies in another country, the Accident Compensation Corporation (the Corporation) can require a claimant to seek damages in that other country[107] before recovery may be had under the Act.[108] However, the other country may not allow such a claim. For example, in Bennett v. Enstrom Helicopter Corp.,[109] the United States Court of Appeals for the Sixth Circuit held, in applying Michigan's choice of laws statute, that the law of New Zealand governed in a diversity tort action and that plaintiff's only remedy was under New Zealand law.[110]

Finally, there is a statute of limitations in the Accident Compensation Act. A claim must be filed in writing within twelve months of accident or death.[111] This bar may be removed, however, if the Corporation finds cause.[112]

### 3. Benefits

The major benefit provided by the Act is earnings related compensation (ERC).[113] ERC is paid to the victim beginning one week after an

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105. *Id.*

106. *Id.* at 258 (quoting Review Decision R 77/1352). Review decisions are delivered by the Accident Compensation Corporation, 3 N.Z. Stat. § 101 (1982). This particular review decision involved the issue of whether a cause of action in products liability for defective drugs survived the Act. Most scholars agree that such an accident is covered by the medical misadventure language of the Act. Therefore common law tort damages are not available.

107. 3 N.Z. Stat. § 86(1) (1982). *See generally* Barlow, *Conflict of Laws, Product Liability and the Substantive Law of New Zealand in Bennett v. Enstrom Helicopter Corp.*, 7 HASTINGS INT'L & COMP. L. REV. 125 (1983).

108. 3 N.Z. Stat. § 86(3)(b) (1982).

109. 679 F.2d 630 (6th Cir. 1982). This holding precludes a tort plaintiff from recovering any substantial damages.

110. *Id. But see* Barlow, *supra* note 107, at 129-30. Barlow argues that the substantive law of New Zealand should have been applied. Thus, the Sixth Circuit should have used New Zealand's common law action for products liability and allowed the plaintiff to proceed.

111. 3 N.Z. Stat. § 98(1) (1982).

112. *Id.* § 98(2).

113. *See id.* § 59.

accident.[114] If the accident was work-related, the victim's employer must pay for the first week of lost wages.[115]

To calculate the amount of ERC available, "earnings" and "relevant earnings" must first be determined. Earnings are defined by specific inclusions and exclusions.[116] It is irrelevant whether the claimant is the employee of another or self-employed; earnings include "wages, salary, allowances, . . . holiday pay, overtime pay, . . . bonuses [and] . . . commissions. . . ."[117]

"Relevant earnings" is a subset of earnings. Relevant earnings are set at a figure determined by the Corporation to "fairly and reasonably represent [the accident victim's] normal average weekly earnings."[118] The Corporation looks first at weekly earnings. If this figure is not representative, the Corporation may then look at the preceding twenty-eight days, or the preceding twelve months.[119] When the injury results in a temporary loss of earning capacity, ERC is payable at the rate of eighty percent of relevant earnings.[120] The ceiling on this payment is $600.00 per week.[121]

A different set of rules applies when the injury results in a permanent incapacity. First, an earner's permanent diminution in capacity to earn must be determined. This figure is calculated by comparing pre-accident and post-accident earning capacity.[122] Next, relevant earnings are multiplied by the percentage diminution in capacity and eighty percent of that amount is paid to the victim.[123] This figure is limited to a ceiling of

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114. *Id.* § 57(6).

115. *Id.* § 59(1). The qualification that an employer pays the first week of lost wages only if the accident was work-related was the result of a large lobbying effort launched by the employers. The first draft of the Act required employers to finance the first week of ERC without regard to the cause of the accident. Employers successfully argued that this obligation would place them under too heavy a burden. *See* G. PALMER, *supra* note 87, at 98.

116. 3 N.Z. Stat. § 52 (1982). The self-employed person receives many exclusions including those for income from dividends, interest, rents, leases, bailments, and easements. *Id.* § 52(3).

117. *Id.* § 52(1).

118. *Id.* § 53(1).

119. *Id.* § 53(2). The Act vests wide discretion in the Corporation and its goal is to fairly compensate all victims.

120. *Id.* § 59(1)-(2).

121. *Id.* § 59(10).

122. *Id.* § 60(2).

123. *Id.* § 60(1)(e). For example, suppose a man has his left hand cut off while fixing his lawn mower. This injury reduces his ability to operate his drill press at work by 20%. His salary pre-injury was $100.00 per week and post-injury is $80.00 per week. He has thus suffered a loss of earning capacity of $20.00 and will receive an ERC of

$600.00 per week.[124]

The Act does not have any provision to account for a worker's potential increase in earnings during his lifetime. In fact, in only certain situations may the ERC account for potential loss of earnings. If an employee is under the age of twenty, an apprentice or in training, an adjustment to the ERC is allowed.[125] At each stage until the age of twenty or until the completion of the apprenticeship or training, the Corporation projects the sum that the employee would have earned.[126]

A different set of criteria is used to determine compensation in the case of death of the victim. The Act authorizes the payment of a lump sum to dependents.[127] A dependent is defined as one to whom a person owed a legal duty of support. Dependency may also arise when the decedent reasonably perceived a moral duty to support another person.[128] The Act contains certain presumptions concerning dependency. A woman is presumed to be totally dependent upon her husband. Similarly, children under sixteen years of age who live at home are considered totally dependent upon their parents.[129]

A surviving dependent spouse is entitled to a lump sum payment of $4,000.00. Surviving dependent children are entitled to lump sum payments of $2,000.00[130] each with a total cap of $6,000.00 to be paid to the children of any one decedent.[131] Dependents are also entitled to receive the proportion of the decedent's ERC that the decedent would have received had he or she lived. A totally dependent spouse is entitled to sixty percent of the ERC that would have been awarded had the decedent been permanently incapacitated. A minor child who is totally dependent will receive twenty percent of the ERC.[132] If both parents of a dependent child die, the minor will receive forty percent of the earner's ERC.[133] A

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$16.00 per week.

124. *Id.* § 60(8).

125. *Id.* § 62(1)(a).

126. *See id.* § 62(1).

127. *Id.* § 82.

128. *See id.* § 2.

129. *Id.* § 85.

130. *Id.* § 82(b)(i). If a spouse or child is only partially dependent, the Corporation may exercise discretion in arriving at a figure. *Id.* §§ 82(a)(ii), (b)(ii).

131. *Id.* § 82(b)(ii). Thus, if there are more than three dependent children, each will receive less than $2,000.00.

132. *Id.* § 65(2)(b). Again, the calculation centers on the distinction between partial and total dependency. If a person was partially dependent, the Corporation decides the degree to which that dependent should continue to receive the decedent's ERC.

133. *Id.* § 65(4). The statute appears only to contemplate payment from one person's ERC.

remarried spouse is entitled to a lump sum equal to two years of ERC in addition to the lump sum paid at the time of death.[134]

Tort lawyers in New Zealand sought and succeeded in obtaining awards for noneconomic losses under the Act.[135] Some typical tort-like awards are still recoverable, but they are highly regulated. A victim can recover against a tortfeasor for the impairment or loss of a bodily function. The Act directs that payment be made in accordance with specified schedules.[136] Thus, many injuries have precalculated recovery values. For example, the total loss of a hand will result in a recovery of $11,900.00. There is a ceiling of $17,000 that may be awarded for any injury.[137] If the victim had a preexisting impairment, the Commission must deduct the percentage that the preexisting impairment comprises of the whole injury.[138]

Other noneconomic losses may be covered. A victim may recover a maximum lump sum of $10,000.00 for "the loss suffered by the person of amenities or capacity for enjoying life, including loss from disfigurement; and . . . [p]ain and mental suffering, including nervous shock and neurosis."[139] Claims for loss of amenities have been hard to sustain. For example, when presented with a rugby player who was injured and could no longer perform at his previous level, the Commission denied his claim for loss of amenities on the grounds that

> [t]he words [of the statute cannot] be read as implying that changes in the way of life on their own should be compensated. For example, men and women reach the stage where they can no longer enjoy the wear and tear on the rugby field. . . . I cannot see in the words [of the statute] any entitlement to compensation. . . .
>
> . . . The legislation is not designed to reward those who are able to lead perfectly normal, healthy, full and active lives.[140]

The final major category of recovery is pecuniary losses. Funeral expenses are the first type of covered pecuniary loss. A claimant may recover funeral expenses that are reasonable by New Zealand's stan-

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134. *Id.* § 70(a). This rule applies only if the beneficiary is under the age of sixty-three. If the beneficiary is between age sixty-three and sixty-five, a lump sum equal to the ERC that would have been paid between the date of remarriage and age sixty-five is awarded. *Id.* § 70(b).

135. *See* Palmer, *supra* note 103, at 25; *see also* G. PALMER, *supra* note 87, at 126; 3 N.Z. Stat. § 79 (1982).

136. 3 N.Z. Stat. § 78.

137. *Id.* § 78(1).

138. *Id.* It may be difficult to separate preexisting impairment from exacerbation.

139. *Id.* § 79.

140. Palmer, *supra* note 103, at 24-25 (quoting Review Decision 75/R0660).

dards.[141] The second type of pecuniary losses recoverable are "actual and reasonable expenses and proved losses necessarily and directly resulting from the injury or death."[142] A number of common law recoveries are specifically excluded. For example, property loss, loss of opportunity to make a profit, and loss from inability to perform a contract are excluded.[143]

### 4. Administration and Appellate Review

A claim for compensation must be submitted in writing.[144] If the accident occurs at work, the claimant must file with the employer; otherwise, the claimant must file with the Corporation.[145] The Corporation then renders its decision on the claim.

Several levels of review are available to a claimant. The first is a review by the Corporation. If the claimant is not satisfied with the Corporation's decision he or she may appeal to the Commission's Appeal Authority. From there, the claimant may go to the Supreme Court, Administrative Division and finally to the Court of Appeal.[146] As a practical matter few cases go beyond the Appeal Authority level.[147]

## B. *Great Britain*

Great Britain still relies on its common law traditions for much of its product liability law. Product liability actions may be brought as breach of warranty, negligence or breach of statutory duty claims. Great Britain is subject to the European Economic Community Directive[148] concerning product liability.

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141. 3 N.Z. Stat. § 81 (1982).
142. *Id.* § 80(1).
143. *Id.*
144. *Id.* § 96.
145. *Id.*
146. *Id.* § 101-12; *see also* Harris, *Accident Compensation in New Zealand: A Comprehensive Insurance System*, 37 MOD. L. REV. 361 (1974).
147. T. ISON, *supra* note 94, at 108.
148. *Council Directive of 25 July, 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products*, 28 O.J. EUR. COMM. (No. L 210) 29 (1985) [hereinafter *Council Directive*]; *see infra* notes 176-91.

### 1. Breach of Warranty

The Sale of Goods and Hire Purchase Act establishes warranties that must accompany all commercial transactions.[149] The Act prohibits implied warranties in contracts for the sale of goods except as specifically provided.[150] First, the Act provides a warranty of merchantable quality.[151] This warrants that the goods are fit for the purpose for which they are commonly bought. This warranty factors in expectations.[152] The warranty of merchantable quality is required in every transaction except when defects are shown to the buyers. If a buyer examines the goods, any defect that should reasonably have been discovered is not under warranty.[153]

The second warranty is a warranty of reasonable fitness for a particular purpose.[154] There are several requirements before this warranty may be enforced. First, the buyer must notify the seller of the particular purpose for which the product is purchased.[155] Also, the buyer must show reliance on the skill and judgment of the seller.[156] Additionally, Britain retains a privity of contract requirement in order for a plaintiff to sustain a breach of warranty suit.[157]

Contractual disclaimers of liability are statutorily invalid in Great Britain. The relevant statute reads: "As against a person dealing as con-

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149. Sale of Goods and Hire Purchase Act, 1979, ch. 54.

150. *Id.* § 14(1). The statute reads: "Except as provided by this section and section 15 below and subject to any other enactment, there is no implied condition or warranty about the quality or fitness for any particular purpose of goods supplied under a contract of sale." *Id.*

151. *Id.* § 14(2).

152. *Id.* § 14(6). The definition of merchantable quality has been a problem for the courts throughout the years. *See* Cehave N.V. v. Bremer Handelsgesellschaft, m.b.H. 1976 Q.B. 44 (C.A.). Moreover, the statute does not prescribe whose expectations are to be judged—those of the consumer or those of the manufacturer.

153. Sale of Goods and Hire Purchase Act, 1979, ch. 54, § 14(2).

154. *Id.* § 14(3).

155. *Id.*

156. *Id.; see* Vacwell Engineering Co., Ltd. v. B.D.H. Chemicals, Ltd., [1971] 1 Q.B. 88. In *Vacwell*, the plaintiff purchased chemicals from the defendant. When the plaintiff washed tubes containing the chemicals, water became mixed with the chemicals and an explosion occurred. The court held there was a two step inquiry to imply a condition of fitness. First, the court asked whether the buyer informed the seller of the buyer's particular purpose. Second, the court asked whether the buyer relied on the seller's skill or judgment. The court found in favor of plaintiff on both issues and allowed recovery. *Id.* at 103-04.

157. Winterbottom v. Wright, 10 M & W 109, 152 Eng. Rep. 402 (1842); *cf.* Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN L. REV. 791 (1966).

sumer, liability for breach of the obligations arising from [section 14] of the [Sale of Goods Act] . . . cannot be excluded or restricted by reference to any contract term."[158] Thus, boilerplate disclaimer provisions may no longer work to the detriment of the ordinary consumer.

An example of the hardship that may result under section 14(3) is demonstrated by *Daniels & Daniels v. R. White & Sons, Ltd.*[159] In *Daniels*, the plaintiff drank some lemonade that had been purchased by her husband which contained carbolic acid. She sued the store owner and the manufacturer. The court held that plaintiff could not recover against the manufacturer because she had not relied on the manufacturer's skill or judgment.[160] Instead, the court imposed liability on the store owner who had no way of detecting the problem with the lemonade.[161]

### 2. Negligence

Until 1932, British tort law did not impose a duty of care upon manufacturers. Because consumers were owed no duty, negligence law was unavailable as a cause of action. Thus, consumers were often without recourse against manufacturers that committed wrongful acts. Because the consumers did not directly purchase the goods from the manufacturer, privity of contract often precluded a breach of warranty action.

This situation changed with the decision of *Donoghue v. Stevenson.*[162] In *Donoghue*, the plaintiff found the remains of a snail in a bottle of ginger beer. The plaintiff was not a purchaser, but merely a consumer, and thus a breach of warranty action was not available. The court, however, imposed a duty of care on the manufacturer. This duty is now known as the "neighbor" rule.[163] In the majority opinion, Lord Atkin reasoned that a manufacturer "must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbor."[164] After *Donoghue*, a victim who wished to pursue a negligence claim needed to prove three elements: the existence of a duty, the breach of the duty, and a causal connection between the breach and the injury.[165]

This new cause of action was helpful to plaintiffs but it was difficult

158. Unfair Contract Terms Act, 1977, ch. 50, § 6(2) (subsection division omitted).
159. [1938] 4 All E.R. 258 (K.B.).
160. *Id.* at 263.
161. *Id.* at 264.
162. 1932 App. Cas. 562 (Scot.).
163. Plummer, *Products Liability in Britain*, 9 ANGLO-AM. L. REV. 65, 69 (1980).
164. *Donoghue*, 1932 App. Cas. at 599.
165. H. TEBBENS, INTERNATIONAL PRODUCT LIABILITY 51 (1979).

to prove a breach of the duty. For example, when a product came from a large manufacturing plant, the plaintiff had a very difficult time proving a lack of care. This problem was solved in *Grant v. Australian Knitting Mills, Ltd.*[166] There, the court laid down the rule that "negligence is found as a matter of inference from the existence of defects taken in connection with all unknown circumstances."[167] The court effectively switched the burden of proof to the defendant to show that the harm was not caused by a lack of care.

The holdings of *Donoghue* and *Grant* have not always been applied consistently to other cases. In *Daniels & Daniels v. R. White & Sons, Ltd.*, the court denied plaintiff's claim based on negligence, but allowed a breach of warranty claim.[168] The court seemed to establish a defense for manufacturers, indicating that they could fulfill their duty of care by using a foolproof process.[169] The facts of *Daniels*, however, are not easily distinguishable from *Donoghue.*

### 3. Breach of Statutory Duty

The Consumer Safety Act of 1978 provided protection to the consumers of numerous products.[170] The Secretary of State is empowered to promulgate regulations which will ensure that adequate levels of safety are maintained for products.[171] The Act, however, expressly excludes

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166. 1936 App. Cas. 85 (P.C.). In *Grant*, the plaintiff purchased underwear. After wearing it, he developed a severe rash. He discovered that the clothing contained excess sulphites. The court found that since the manufacturing process was foolproof, someone must be at fault. *Id.* at 101.

167. *Id.*

168. [1938] 4 ALL. E.R. 258 (K.B.).

169. *Id.* at 261-62. In contrast, the relevant German code provision states:

> A person who employs another to do any work is bound to compensate for any damage which the other unlawfully causes to a third party in the performance of his work. The duty to compensate does not arise if the employer has exercised necessary care in the selection of the employee, and, where he has to supply apparatus or equipment or to supervise the work, has also exercised ordinary care as regards such supply or supervision, or if the damage would have arisen notwithstanding the exercise of such care.

2 BGB § 831 (originally enacted, January 1, 1900), *translated in* THE GERMAN CIVIL CODE 136 (I. Forrester, S. Goren, H.-M. Ilgen trans. 1975) (including translation of amendments through 1975) [hereinafter GERMAN CODE]. This section establishes a major defense for German manufacturers similar to the foolproof process defense found in British law.

170. Consumer Safety Act, 1978, ch. 38.

171. *Id.* The Act states that "[t]he Secretary of State may make regulations containing such provision . . . as . . . appropriate for the purpose of securing that goods are safe.

medicinal products from its coverage.[172] These products are regulated by the Food and Drug Act and the Medicine Act,[173] neither of which creates a private cause of action.[174]

### 4. European Economic Community Directive

Members of the European Economic Community (EEC) have sought to unify their laws on product liability for many years.[175] At the end of July 1985, the Council of European Communities addressed a Directive to the member states.[176] This Directive seeks to impose strict liability on producers for damage from defective products.[177]

The EEC believed that there were many flaws in the product liability laws of the member countries. The Directive adopted three main goals: elimination of the distortion in competition among member countries; the promotion of free trade; and the promotion of equal and adequate consumer protection.[178]

Article 1 imposes liability on a producer "for damage caused by a defect in his product. "[179] Through this language, the Council attempted to impose liability without fault, that is strict liability.[180] The Directive defines a defective product as a product that does not meet consumers' safety expectations.[181] Presentation of the product, use, and time of circulation are factored into the determination of whether a product is defective.

Article 4 provides a private cause of action. A claimant must prove

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. . ." *Id.* § 1(1); *see also* Plummer, *supra* note 163, at 74-75.

172. Consumer Safety Act, 1978, ch. 38, § 9(4)(b). The Act excludes drugs from its provisions.

173. *Id.*

174. Plummer, *supra* note 163, at 76; *see also* Square v. Model Farm Dairies, Ltd., [1939] 2 K.B. 365.

175. *See generally* HARMONIZATION OF LAWS IN THE EUROPEAN COMMUNITIES: PRODUCTS LIABILITY, CONFLICT OF LAWS AND CORPORATION LAW (P. Herzog ed. 1983) (papers presented at the Fifth Sokol Colloquium) [hereinafter HARMONIZATION].

176. *Council Directive*, *supra* note 148, at 29.

177. *Id.* The preamble of the Directive repeatedly states that the imposition of liability without fault is the only way to solve the products liability crisis.

178. *Id. See generally* Note, *Products Liability: A Comparison of U.S. and EEC Approaches*, 13 SYRACUSE J. INT'L L. & COM. 155 (1986).

179. *Council Directive, supra* note 148, art. 1. "Product" is defined as "all movables." However, the Directive excludes agricultural products from the definition of product, unless they are manufactured industrially. *Id.* art. 2.

180. *Id.* Preamble.

181. *Id.* art. 6. *See generally* Albanese & Del Duca, *Developments in European Product Liability*, 5 DICK. J. INT'L L. 193 (1987).

"damage, the defect and the causal relationship."[182] After the plaintiff establishes a prima facie case, the defendant has several enumerated defenses. A producer will not be liable if: the defect did not exist at the time of circulation; the product was not circulated by this manufacturer; or the state of knowledge at the time of circulation would not allow the discovery of the defect.[183] In addition, the Directive seeks to solve the problem that arises when the producer of a product is unknown[184] and seems to impose liability jointly and severally on all the suppliers.[185]

The Directive also attempts to ameliorate a common discovery rule problem that occurs in tort cases by imposing a three-year statute of limitations.[186] This limitations period is tolled until the victim is aware, or should have been aware of the defect, damage, and identity of the producer.[187] The Directive also contains a ten-year statute of repose.[188]

Member states are allowed to impose ceilings on recovery, but they must not be lower than seventy million ECU.[189] The Directive is to be implemented by July of 1988.[190] Some have argued that the Directive does not truly embrace strict liability, but rather contains a negligence inquiry.[191] If such an interpretation is accurate, then Britain is already in compliance with the Directive.

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182. *Council Directive, supra* note 148, art. 4.

183. *Id.* art. 7. The British pushed hard for the development risk defense found in Article 7(e). M. WILL, *Asides on the Nonharmonization of Products Liability Laws in Europe*, in HARMONIZATION, supra note 175, at 32-37. Article 15 of the Directive allows a member state to void this defense. If they choose to follow this route the commission must be notified and the effects tracked. *Council Directive, supra* note 148, art. 15.

184. *See, e.g.*, Sindell v. Abbott Laboratories, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980) (DES victims allowed to recover against industry as a whole).

185. *See Council Directive, supra* note 148, art. 3(3).

186. *Id.* art. 10.

187. *Id.*

188. *Id.* art. 11.

189. *Id.* art. 16. An ECU is a European Currency Unit that is used for settling debts in the EEC. D. LASOK, THE LAWS OF THE ECONOMY IN THE EUROPEAN COMMUNITIES 161 (1980).1

190. *Council Directive, supra* note 148, art. 19.

191. *See, e.g.*, Stapleton, *Products Liability Reform—Real or Illusory?*, 6 OXFORD J. LEGAL STUD. 392, 420-21 (1986) (argument that existence of defect still depends on a cost benefit inquiry, which also is essentially a negligence inquiry).

## C. *West Germany*

### 1. Breach of Warranty

Since 1900, West Germany has been governed by a civil code.[192] Thus, all laws relating to product liability are codified. Like Great Britain, West Germany adheres to the rule that a victim must be in privity of contract with the seller to maintain a breach of warranty action.[193] This rule will bar most tort victims from suing a manufacturer for a defective product. The main warranty provisions of German sales law are found in section 459 of the Bürgerliches Gesetzbuch (BGB). A seller has the duty to warrant that there are no latent defects in the product and that the product contains its promised qualities.[194] A purchaser may only claim damages if the promised quality is lacking, or if the seller fraudulently concealed the defect.[195]

One impediment to a buyer's recovery is the requirement that the warranty be express.[196] A buyer is thus generally precluded from claiming implied warranties.[197] Moreover, a seller is not liable for breach of warranty if a buyer knew or should have known of the defect.[198] This rule is inapplicable, however, when the seller has fraudulently concealed a defect.[199] A final obstacle to recovery under breach of warranty is that a seller may validly disclaim liability. The statute voids such disclaimers only if the defect is fraudulently concealed.[200]

Various quasi-contractual causes of action have also been proposed in West Germany. These include: contracts for the benefit of third parties; contracts establishing direct legal relationships between manufacturers and consumers; and, a form of liability based on representations by manufacturers to the public at large. However, these theories have not been widely followed by German courts and ultimately have been rejected by

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192. GERMAN CODE, *supra* note 169, at xi.

193. H. TEBBENS, *supra* note 165, at 69.

194. 2 BGB § 459; *see also* GERMAN CODE, *supra* note 169, at 72-73.

195. 2 BGB § 463. The section reads: "If a promised quality in the thing sold was absent at the time of the purchase, the purchaser may demand compensation for nonperformance, instead of cancellation or reduction. The same applies if the seller has fraudulently concealed a defect." *Id.; see also* GERMAN CODE, *supra* note 169, at 73.

196. H. TEBBENS, *supra* note 165, at 67.

197. *Id.*

198. 2 BGB § 464; *see also* GERMAN CODE, *supra* note 169, at 73.

199. 2 BGB § 464; *see also* GERMAN CODE, *supra* note 169, at 73.

200. 2 BGB § 476. The section reads: "An agreement, whereby the obligation of the seller for warranty against defects in the object is released or limited, is void, if the seller fraudulently conceals the defect." *Id.; see also* GERMAN CODE, *supra* note 169, at 74.

the German Supreme Court.[201]

### 2. Negligence

The West German law of torts is codified in the BGB under the heading entitled "delict." Section 823 sets out the main duty: "A person who, willfully or negligently, unlawfully injuries the life, body, health, freedom, property or other right of another is bound to compensate him for any damage arising therefrom."[202] The basic elements of the cause of action are a violation of an enumerated interest, culpability and cause.[203] The enumereated interests have been broadly construed. For example, the categories of life, body and health include death or any adverse interference with one of those categories.[204] An infringement of a person's right to freedom of movement constitutes an infringement of "freedom."[205] Finally, the ownership rights of property are protected.[206]

Culpability is composed of two elements: unlawfulness and fault. The majority view is that the element of unlawfulness is satisfied whenever an enumerated right has been infringed.[207] According to this view, any damage to the victim's body would satisfy the requirement of unlawfulness. This rule has been criticized by scholars as being result oriented.[208] Fault is defined by statute in terms of negligence: "A person who does not exercise ordinary care acts negligently."[209] Such a concept is very similar to that found in common-law countries.

Causation in German law is broken down into two elements. Both a "but for" causal element as well as proximate cause must be established by the plaintiff.[210] "But for" causation is simply the common sense notion that the conduct caused the result, whereas proximate cause involves policy and value judgments. A jury must find that the tortfeasor's conduct significantly increased the risk of harm to the victim.[211] This position is a middle ground between conduct that is the simple cause in fact

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201. *See* H. TEBBENS, *supra* note 165, at 70-72.

202. 2 BGB § 823; *see also* GERMAN CODE, *supra* note 169, at 134.

203. B. MARKESINIS, A COMPARATIVE INTRODUCITON TO THE GEMERAN LAW OF TORTS 24 (1986).

204. *Id.* at 25-27.

205. *Id.* at 27.

206. *Id.* at 28.

207. *Id.* at 40.

208. *Id.* at 41. These scholars feel the conduct itself should be analyzed to find unlawfulness. *Id.*

209. 2 BGB § 276; *see also* GERMAN CODE, *supra* note 169, at 46.

210. B. MARKESINIS, *supra* note 203, at 64.

211. *See id.* at 67-68.

of the harm and conduct in which the harm was simply foreseeable.[212]

Prior to 1969, the products liability plaintiff bore the difficult burden of proving that a manufacturer was negligent. Moreover, the judicial construction of section 831, a due care exception to liability, proved to be a virtually insurmountable hurdle. The courts transformed this section into what is, in essence, an absolute defense for manufacturers. So long as the manufacturer carefully selected and supervised its management, courts would not hold the manufacturer liable for product liability under section 823.[213] Consequently, plaintiffs had a dismal chance of recovery in such cases.

However, in *Fowlpest*, the supreme court removed these obstacles.[214] In *Fowlpest*, a farmer had a veterinarian inject his chickens with a drug to combat the disease of fowlpest. Instead of preventing fowlpest, many of the chickens contracted the disease, over 4,000 of which died. The farmer brought suit against the vaccine manufacturer. The court held the manufacturer liable under section 823.[215]

First, the court considered the various contractual provisions of the BGB. The court concluded that a breach of contract action was not available to the farmer because he was not in privity with the manufacturer. The court also rejected the plaintiff's proposed quasi-contractual theories on the ground that the legal relationships were too tenuous.[216]

The court then turned to section 823. Realizing that section 831 posed an often insurmountable defense for manufacturers in product liability cases, the court reversed the burden of proof.[217] Now, a plaintiff must show merely a casual link between the product and the damage.[218] In

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212. *Id.*

213. 2 BGB § 831(1), which states:

> A person who employs another to do any work is bound to compensate for any damage which the other unlawfully causes to a third party in the performance of his work. The duty to compensate does not arise if the employer has exercised necessary care or the selection of the employee, and, where he has to supply apparatus or equipment or to supervise the work, has also exercised ordinary care as regards such supply or supervision, or if the damage would have arisen notwithstanding the exercise of such care.

*See also* GERMAN CODE, *supra* note 169, at 136.

214. Judgment of Nov. 26, 1968, Bundesgerichtshof, W. Ger., 51 Bundesgerichtshof in Zivilsachen [BGHZ] 91 [hereinafter *Fowlpest*], *translated in* B. MARKESINIS, *supra* note 203, at 245; *see also* Mankiewicz, *Products Liability—A Judicial Breaktrough in West Germany*, 19 INT'L & COMP. L.Q. 99 (comments on *Fowlpest*, *supra*).

215. B. MARKESINIS, *supra* note 203.

216. *Id.* at 247-48.

217. *Id.* at 252-54; *see also* Mankiewicz, *supra* note 214, at 99-100.

218. Mankiewicz, *supra* note 214, at 112-13.

defense, the defendant manufacturer must prove absence of fault. The court held that because the defect is within the manufacturer's "sphere of risk," it was "appropriate and equitable that he carry the risk of not being able to prove absence of fault on his part."[219] In essence, the law presumes liability on the defendant and it is the defendant's burden to rebut this presumption.[220]

### 3. Strict Liability

In 1976, West Germany passed regulations that dealt with liability for defective pharmaceuticals.[221] Section 84 of the BGBl imposes liability on a pharmaceutical manufacturer in a number of situations. A manufacturer is held liable when the prescribed use of the medicine has injurious effects that go beyond accepted medical standards.[222] The defect must arise in the development or manufacture of the product. Also, manufacturers are liable if their directions for the use of their products are not in conformity with accepted standards.[223]

Recovery against the manufacturer is diminished by any contributory fault of the plaintiff and is completely barred if the drug is not used in conformity with the manufacturer's directions.[224] Plaintiffs may file a claim for up to three years from the time they gain knowledge of their injuries.[225] Also, manufacturers cannot absolve themselves of liability through an exculpatory clause.[226]

In the event of death, a victim's estate may recover the costs of the victim's treatment, loss of earnings, funeral expenses, and any support the decedent legally owed to any dependent.[227] If the drug causes only personal injury, a victim may recover the costs of treatment, any finan-

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219. *Id.* at 113.

220. *Id.*

221. Arzneimittelgesetz, 24 August 1976, BGBl. I §§ 84-94 [hereinafter BGBl.I]. For a translation, see *infra* Appendix at 839.

222. BGBl.I, *supra* note 221, at §§ 84(1).

223. *Id.* § 84(2).

224. *Id.* § 85. The statute states: "If the negligence on the part of the injured individual contributed to the occurrence of the injury, then § 254 of the Civil Code shall apply." *Id.* Section 254 of the German Civil Code states that "[i]f any fault of the injured party has contributed to causing the damage, the obligation to compensate the injured party and the extent of the compensation to be made depends upon the circumstances, especially upon how far the injury has been caused predominantly by the one or the other party." 2 BGB § 254(1); *see also* GERMAN CODE, *supra* note 169, at 42; Fleming, *Drug Injury Compensation Plans*, 30 AM. J. COMP. L. 297, 300 (1982).

225. BGBl.I, *supra* note 221, at § 90.

226. *Id.* § 92.

227. *Id.* § 86(1).

cial damages and an amount representing any reduction in capacity to earn.[228] The statute imposes ceilings on these awards. If the drug injures only one person, there is a lump sum cap of 500,000 deutsche marks ("DM"), or an annuity of DM 30,000 per year. If more than one person is injured, a lump sum cap of DM 200 million is imposed, or a cap on annuities of DM 12 million per year.[229]

Section 91 allows for concurring of actions under the strict liability statute and the civil code remedies.[230] Finally, pharmaceutical manufacturers must insure themselves against potential loss.[231]

## IV. CONCLUSION

The varied laws of foreign countries pose distinct advantages and problems for United States pharmaceutical companies exporting unapproved drugs. These laws create incentives and disincentives to export drugs that have no true social value.

First, West Germany's strict liability statute should promote cautiousness among domestic pharmaceutical producers. When shipping unapproved drugs to West Germany, a producer faces a heavy risk of liability. Such a result is proper because United States producers should not be given free license to ship unapproved drugs to foreign countries if those drugs are dangerous. Granted, these drugs must be approved in the receiving country as a condition precedent to shipping, but there are faults inherent in approval processes as demonstrated by the disastrous harm caused by thalidomide, an approved drug.

In contrast, Great Britain's laws may encourage irresponsibility toward British drug consumers. An American producer could easily rebut the presumption of negligence in a drug product liability case. A foreign plaintiff will find it difficult to procure evidence for a trial. It would be very expensive to hire local counsel and investigators to engage in a fact-finding mission on another continent. This cost along with no guaranty of success at trial will discourage many potential plaintiffs from filing a product liability suit. The alternative of bringing suit in an American court will likewise be very expensive. This large expense may very well preclude recovery. As a result, injured parties may effectively be without remedy when a significant harm has been suffered. The goals of tort law do not favor this result—neither should a United States statute.

New Zealand appears to be the worst case scenario. New Zealand's

228. *Id.* § 87.
229. *Id.* § 88.
230. *Id.* § 91.
231. *Id.* § 94.

no fault system completely insulates domestic pharmaceutical producers from liability for injury to drug consumers. This essentially provides United States producers with an unrestricted testing ground for new drugs. Given the decision of the United States Court of Appeals for the Sixth Circuit in Bennett v. Enstrom Helicopter Corp.,[232] even a wealthy New Zealander has no recovery under United States law. This decision should be reconsidered. By enacting the DEAA, Congress did not intend to create new areas for the testing of drugs. Rather, it intended to equalize competitive markets for drugs worldwide. Therefore, when a country chooses to abolish tort liability, the exporter's country should not insulate the tortfeasor. If a manufacturer's drugs cause harm, meaningful compensation for that harm must be recoverable. Thus, the DEAA poses a significant hazard to New Zealanders who consume drugs imported from the United States. Not only must they be wary of imported drugs, but they must be aware that if injury occurs, they may receive no adequate compensation.

*James C. Grant*

232. 679 F.2d 630 (6th Cir. 1982).

## APPENDIX**

### Section Sixteen
### Liability for Injuries from Pharmaceutical Products

### § 84
### Absolute Liability

If an individual has been killed or the body or health of an individual has been significantly injured as the consequence of the use of a pharmaceutical product intended for use in humans, a product which has been supplied to the consumer within the territorial scope of this law and which is subject to the obligation of being officially approved or is exempted from official approval by government ordinance, then the pharmaceutical entrepreneur who has put this pharmaceutical product on the market within the territorial scope of this law is obligated to compensate the injured individual for the resulting injury. The liability for damages exists only if

1. the pharmaceutical product, when used as prescribed, has injurious effects that exceed the degree that is justifiable according to the findings of medical science and that have their cause in the area of development or manufacture, or
2. the injury occurred as the result of labeling or information regarding use that did not correspond to the findings of medical science.

### § 85
### Contributory Negligence

If negligence on the part of the injured individual contributed to the occurrence of the injury, then § 254 of the Civil Code shall apply.

### § 86
### Extent of Liability for Damages in the Event of Death

(1) In the event of death, damages must be paid through reimbursement of the expenses of an attempted treatment and also of the pecuniary prejudice that the deceased individual has suffered as a result of the fact that during the illness his earning capacity was eliminated or reduced or an increase in his needs had occurred. The individual liable for damages must furthermore reimburse for burial expenses the individual whose obligation it is to bear these expenses.

(2) If the deceased individual was in a relationship with a third party at the time of the injury, whereby he was or could become legally responsible for support of this party, and if the third party has been deprived of the right to support as a consequence of the death, then the person liable for damages must pay the third party damages to the extent

** Translated by Judith Lee, Ph.D., Language Services, Knoxville, Tennessee.

to which the deceased, during the probable duration of his life, would have been obligated to provide support. The liability for damages also exists if the third party was conceived but not yet born at the time of the injury.

§ 87

**Extent of Liability of Damages in the Event of Bodily Injury**

In the event of injury to body or health, damages must be paid through reimbursement of the expenses of successful treatment and of the pecuniary prejudice which the injured individual suffers by the fact that his earning capacity is eliminated or reduced temporarily or permanently or an increase in his needs has occurred as the result of the injury.

§ 88

**Maximum Amounts**

The person liable for damages is liable

1. in the event of the death of injury of one individual, for a maximum capital amount of five hundred thousand German marks [Deutsche Mark] or a maximum annuity amount of thirty thousand German marks per year,

2. in the event of death or injury of several individuals from the same pharmaceutical product, irrespective of the limits defined in No. 1, for a maximum capital amount of two hundred million German marks or a maximum annuity amount of twelve million German marks per year. If the compensations to be paid to several injured individuals in the event of Paragraph 1, No. 2, exceed the maximum amounts stipulated in that clause, then the individual compensations are reduced in proportion to the ratio of their total amount to the maximum amount.

§ 89

**Damages in the Form of Annuities**

(1) Damages due to loss of or decrease in earning capacity and due to increase in the needs of the injured individual and damages to be paid to a third party in accordance with § 86, Subsection 2 shall be paid for the future by payment of an annuity.

(2) The provisions of § 843, Sec. 2-4, of the Civil Code and of § 708, No. 6 of the Code of Civil Procedure shall apply accordingly.

(3) If, when the liable party is adjudged to pay an annuity, no requirement to furnish security has been imposed, the beneficiary shall nevertheless be able to demand security if the financial condition of the liable party has worsened considerably; under the same conditions he can demand an increase specified in the judgment.

§ 90

**Limitation of Actions**

(1) The claim defined in § 84 is subject to a limitation of three years from the date on which the individual entitled to damages obtains knowledge of the damage, of the conditions from which his right to a claim results, or of the person of the individual liable damages, [or,] irrespective of this knowledge, of thirty years from the injurious event.

(2) If negotiations regarding the damages to be paid are in progress between the individual liable for damages and the individual entitled to damages, then the limitation period is extended until one or the other party refuses continuation of negotiations.

(3) Otherwise the provisions of the Civil Code regarding limitation of actions shall apply.

§ 91

**More Extensive Liability**

Legal regulations according to which an individual liable for damages under § 84 shall be liable to a greater extent than specified by the provisions of this section, or according to which another individual is responsible for the injury, shall not be affected by this act.

§ 92

**Absoluteness**

Liability for damages in accordance with this section may not be excluded or limited in advance. Any contrary agreements shall be null and void.

§ 93

**Several Individuals Liable for Damages**

If several individuals are liable for damages, then they are jointly and severally liable. In the same proportion as that of the persons liable for damages to one another, the liability for damages and the extent of the damages to be paid depend on the conditions, particularly on the extent to which the injury has been caused primarily by the one or the other party.

§ 94

**Provision for Sufficient Cover**

(1) The pharmaceutical entrepreneur must provide for the possibility that he must fulfill his legal obligations to pay damages arising from the use of a pharmaceutical product intended for use in humans that he has put on the market, a product subject to the obligation of being officially approved or exempted from official approval by government ordinance (provision for sufficient cover). The provision for sufficient cover must be in the amount of the sums specified in § 88 Sec. 1. It can be provided only

1. by liability insurance with an insurance company authorized to do business within the territorial scope of this law or

2. by an indemnity or guarantee obligation from a domestic banking institution.

(2) If sufficient cover is provided by liability insurance, then §§ 158c-158k of the Law on Insurance Policies of May 30, 1908 (Reich Law Gazette, p. 263), last amended by the Law of June 30, 1967 (Federal Law Gazette I. p. 609) shall apply correspondingly.

(3) The provision for cover can only be provided by an indemnity or guarantee obligation from a banking institution if it is guaranteed that, for the period in which recourse to the banking institution is expected, the banking institution will be capable of meeting its obligations within the scope of the provision for cover. §§ 158c and 158k of the law of Insurance Contracts shall apply correspondingly to the indemnity or guarantee obligation.

(4) The competent body as defined by § 158c, Subsection 2, of the Law on Insurance Policies is the competent authority for carrying out supervision in accordance with § 64.

(5) Neither the Federal Republic of Germany nor its states (Lander) are obligated to provide cover as defined in Subsection 1.