

同様である。蓋然性が、健康被害の原因となる因果関係（の立証）に少なくとも不利に働かず、有利な証拠になる状況が優勢であれば因果関係が成立するということである。

この蓋然性の基準は、「予防接種」→「健康侵害」→「接種被害」というフローの「予防接種」と「健康侵害」の因果関係にも適用される。

因果の連鎖に関しては十分に確かで、事実の根拠がなくともいい一方で、構成要素（＝「予防接種」、「健康侵害」、「接種被害」の3つ）については、一つ一つに完全な立証が必要となる。これはほぼ確実性に近く、重大で合理的な疑いを排除する程度の蓋然性を求めることになる。この要求は蓋然性よりも司法による確信の形成（Überzeugungsbildung）をより強く求めるものである。「健康侵害」が立証されていなければ、因果の連鎖の最後の構成要素である「健康被害」との因果関係を調べることは不要となる。

立証責任の転換はこの分野には存在せず、被害者が、因果の連鎖の構成要素の1つ1つについて、及び因果関係の蓋然性について立証責任を負う。

第2文は、連邦援護法§1(3)（第2文）に相当する。立証された長引く疾患の原因に関し、医学上の不確実性の存在が、被害者に完全に不利になってはならないという趣旨のものである。

疾患の発生原因について様々な医療上の学説があり一貫していない場合、医学上の不確実性が存在することになる。こうした健康侵害の発生原因に関し（＝健康被害との因果関係の蓋然性につき）医学上の不確

実性が存在する際に健康被害を認定するには、州の戦争犠牲者援護を所管する上級の行政官庁に判断を仰ぐ「裁量規定」が重要な役割を果たす（第2文後段～第3文）。州の上級行政官庁の同意があれば、医学上の不確実性が存在したとしても、健康被害を認定できる。この同意は、一般的に許可される。

第4文は、健康侵害が疑いなく予防接種等を原因としないことが明らかになった場合には、過去の健康被害の認定が取り消されることがあることを規定している。この取り消しに関しては期限が特に設けられていない。

(2) 5. 第62条

この規定は、連邦援護法の規定による諸給付以外に、予防接種被害救済において付加的な給付を行うことを定めるものである。被害者の大方が若年者であることを考慮し、治療養護教育的措置（共同社会及び環境との結びつきを受容する機会を与えることを目的とし、教育及び訓練を通じ、心身発達を促進するもの）、健康治療体操、運動療法が提供されることを規定している。

(2) 6. 第63条

第1項は、連邦援護法に基づき生じた他の諸請求権との競合を調節する規定である。調節される請求権は、連邦援護法、（被）抑留者扶助法、刑法上の更生、行政法上の更生、軍人恩給法、非軍事役務法、犯罪被害者補償法の請求権である。その際には、生業能力の低下を考慮した上で、年金が一括して支払われることになる。この

評価基準は連邦援護法 § 30に規定されている。

公務員の過失による職務上の義務違反の場合には、第2項により、感染症法 § 60の援護請求権と同時に、民法 § 839(1)による被害者の職務責任請求権（公務員個人に対するもの）が存続することとなる。民法 § 839(1) 2文には、公務員が（故意ではなく）過失であった場合は、「他の方法で補償が得られない場合だけ」職務責任が発生するとされているが、この第2項は民法 § 839の例外規定となっている²⁸。

第3項は労災保険（社会法典第7編）との適用関係を示しており、援護法よりも高い給付が受けられる労災保険の給付が受けられなくなるのを避けるようにした条文である。

第4項は、この法に基づく第三者の請求権が国に譲渡された場合の規定の適用についての条文である。

第5項は、連邦援護法 § 89に規定する「特別な苛酷」（Härte）に対し調整する給付を、予防接種被害救済に関しても認める、という規定である。この苛酷緩和調整は、個別事例において法律の規定をそのまま適用すると特別に苛酷な事態が生じる場合に連邦労働社会省（予防接種被害救済の場合には戦争犠牲者援護に関する州の最高機関）の承認を得て、これを調整する給付を支給するものである。この苛酷緩和調整が設けられているのは、事例の特殊性のために立法者が見逃すか、予期しないか、十分に区分して規定しなかったような場合の

ためであり、立法と行政の制度上の境界を侵害してしまわないように、特別の例外的事例に限定されている²⁹。

第6項は、医療費に関する疾病金庫への補填を定めた連邦援護法第20条の準用を定めたものである。

第7項、第8項は、医療費の支払いに関する経過規定である。

（2）7. 第64条

第1項は、予防接種被害補償に関する規則の実施は、連邦援護法の施行を管轄する官庁（援護事務所）が管轄することを定めている。援護事務所の管轄区域については、補償給付を支払う州政府が命令により定めることとする一方、州政府は命令により他の行政組織に権限をゆだねることができるとされている。

所管の援護事務所は、事実関係を明確化させ（場合によって鑑定人を介在させる）、評価を行った上で援護申請について判断を下すこととされている。（「戦争犠牲者援護給付に関する行政手続法」 § 12以下に規定）

第2項は、給付等手続きに関し、「戦争犠牲者援護給付に関する行政手続法」、社会法典第10、社会裁判所法等の関連条項が適用されることを規定している。第3項は

²⁹ ドイツ研究会 (1993), P486. この規定に関し、Bales, et.al.では、過去の裁判の判断として、「例えば連邦軍の兵士に外国滞在が業務として指示され、外国において接種が強制、若しくはその地で公的に勧告されていた場合、外国で実施された予防接種の被害についてはドイツ連邦州に対する補償要求とはならない」旨紹介している。(P361)

²⁸ 民法 § 839に関し、脚注22参照。

第2項の例外として、連邦援護法 § 25から § 27eに基づく戦争犠牲者救済の給付等に関する手続きが除外され、これらに代わって行政手続法及び行政裁判所法の規定が適用されることを規定している。

(2) 8. 第66条, 第67条

第66条は第2項において、予防接種被害救済に際しての支払いを誰が行うかを規定しており、第3項においては、§ 63の規定により統合されて支払われることになる「一括された年金」の給付の際の支払者について規定している。

第2項第1号は、§ 60(1) (通常予防接種被害救済)の際には、接種被害が起きた場所の州が負担することを規定する。

第2号は、国外で予防接種を受けた際にどの州が負担するかについての詳細を定めている。

第3号は、国外で天然痘の予防接種を受けた際等にどの州が負担するかについての詳細を定めている。

第67条は第2項において、感染症法 § 60, § 62, § 63に基づく請求(権)の譲渡、担保(pledging), 差し押さえ(attachment)については連邦援護法の規定に従うことを規定している。

(2) 9. 第68条

第68条では、第2項及び第3項において予防接種被害救済に関する出訴について規定している。

第2項においては、基本的に、感染症法 § 60から § 63の第1文に関しては社会裁判所(social court)に訴訟を起こす手段が開かれていることが規定されている。提訴

前には、まず援護事務所の通知に対して異議申し立てを行い、社会裁判所法第77条以下の規定に従い、異議審査手続きをしなければならない(州援護事務所の異議採決による異議決定)³⁰。

一方で、連邦援護法の一貫した解釈を保証するため、§ 68(3)において、連邦援護法 § 25から § 27eに規定する給付(リハビリ、疾病援助、介護援助、休養援助など)に関する訴訟については行政裁判所(administrative court)に出訴することとされている。

接種被害の被害者が予防接種を行った医師に対し訴訟を起こす場合には、正規の法的手段をとることができる(例えば、公職にある医師に対し、民法 § 823, § 847若しくは基本法 § 34, 民法 § 839など³¹)。

(2) 10. 第69条

第69条は第5項で、§ 20(5)の規定に基づき州政府が特定の感染症に対する予防接種を無償で行うことを決めた場合に、その費用負担は州政府が行うことを規定している。

³⁰ 社会裁判所法第77条以下はいわゆる前置手続についての規定である。木佐他(1990)においては、§ 78(2)において、前置手続の例外規定が設けられており、その1つに戦争犠牲者援護事件については前置手続をとらずとも取消訴訟が許されるとされているが、現行法においては社会裁判所法 § 78(2)は空白となっている。(ドイツ法務省ホームページhttp://www.gesetze-im-internet.de/sgg/_78.html) おそらく改正が行われ、コンメンタールの記述は現行法に則したものと思われるが、社会裁判所法 § 78の改正の経緯等については調査が及ばなかった。

³¹ 脚注19から22参照。

(3) 検討及び結語

今回の文献調査により、ドイツ感染症法の予防接種制度及び被害救済制度について、法体系に則して一定の理解を行うことができた。制度の具体的なあり方については既存文献が存在するが、その条文の裏付けに関しては、コンメンタールの訳出を用いることで明確になった点が多くあった。また、予防接種を行った医師の責任は排除されず、予防接種被害救済制度とは別に訴訟も提起しうること等、一般訴訟との関係についても一部明らかにすることができた。

ドイツの制度体系を概観した結果、いずれも自明のことではあるが、その特徴として、以下のことが指摘できる。

①州政府に勸奨、補償両面において相当広範な権限が与えられていること：連邦政府の機関であるRobert Koch Instituteに設置される予防接種委員会（STIKO）が行う勸奨は、州政府がそれに基づいた州ごとのスケジュールを作成したうえでないと、規範性を持つことにならず、被害救済の対象にもならないこと、また、勸奨スケジュールを決定する権限とともに、自らが決めたスケジュールに基づき発生した被害救済の決定や費用負担についても自らが責任を持つなど、分権性が徹底している。この点は、保健医療福祉の他の分野における分権性と共通するものであり、ドイツでのあり方としては至極当然なものであろう。一方で我が国では、条文上接種の実施も被害救済給付の実施も市町村長の権限となっているが、被害救済の審査は国で行われるなど、国の権限と責任はドイツに比べ重

く、担う事務も比較的多いように思われる。予防接種被害救済に係る審査等の事務は、被害事例数に鑑み他の行政事務に比べ国全体でのボリュームが相対的に少ないものであるが、ドイツの場合は被害救済審査等も基本的に連邦援護法に基づく審査等と同じ州組織において運営されており、単に予防接種だけを扱うものではないため、効率性の問題は少ないものと推測される。

②連邦援護法が感染症法を初めとした「国家共同体が、公的な措置により犠牲になった個人の健康被害を補償するための法令」のいわば一般法として機能していること：連邦援護法において対象としている戦争公務や平時の軍務等、あるいは犯罪被害者への補償など他の法令で感染症法と同様に連邦援護法を援用しているものに一貫しているのは、「社会」なるもの～国防のような、国家社会の存立を維持するような営みから、犯罪被害者補償のような犯罪行為まで～の犠牲になった個人に対して、「社会」全体で補償しましょう、という思想である。「社会的補償権」の思想と言ってもいいのかもしれない。予防接種に関しては、それが個人の健康を守るために行われるものなのか、それとも社会における疾病のまん延を防ぐためのものなのか、といった根本論についての議論があり、今日に至るまで結論が出ていない。むしろその両者のバランスを取りながら発展していくべきものなのかもしれない。ドイツにおいても、感染症法の中で予防接種についての義務付けは今では一切行われておらず、あくまでも勸奨接種であることはわが国と同一であるが、わが国の「一類」等に対する予

防接種の努力義務のような規定はない一方で、保育所等の公共施設の雇用主への教育義務などを課すことによって予防接種の接種率や社会全体での免疫防御を向上させるための規定を種々設けている（(2) 2. 2. 参照）。両国においてその体系に応じた形で両者のバランスを確保しながら運営されていることが理解されるが、ドイツにおいては個人に直接アピールするというよりは、社会における周辺環境の方に努力義務を課し、そこからの影響により個人が接種への理解と意欲を持つよう促す、というルートで進めていることが理解される。

とはいえ、給付に関わる内容の多くを、「社会」なるものの犠牲になった個人を救済する一般法の位置づけにある戦争犠牲者を救済するための連邦援護法を借りて、同等の運用になるように実務上も担保されているということは、予防接種は基本的に社会防衛のために行うものであり、そこでの被害の救済は、社会防衛の犠牲になった者への救済である、という哲学が、個人の権利を尊重する種々の規定の基盤に存在するようにも思料される。

また、加害事由を問わず、同程度の障害であれば同程度の給付がいわゆる「並び」で提供されることになり、脚注20の唄・宇都木（1972）の指摘のように、予防接種被害等の障害を負った原因が何であれ、「障害を負った状態があり、その原因が『社会』にあるため、それを公的に援護する」という点が主眼に置かれており、その原因が予防接種であるかどうかについては、法体系としては、二義的であるとも指摘することができる。

③健康侵害と被害との因果関係について比較的積極的に認める等、被害者救済に前向きな姿勢を明文化させていること：特に§61の規定において、事実関係自体の認定は厳格であるとはいえ、被害との因果関係に関しては蓋然性をもって足りることが明文化されており、かつ州の上級行政官庁の同意があれば、医学上の不確実性が存在したとしても、健康被害が認定され、この同意は、一般的に許可されることも明文化されている。こうした姿勢は、被害者救済にとって実質的にプラスであることに加え、(2) 2. 2. で列挙した啓蒙のための規定と同様、「何かあったとしても社会が補償措置を講ずるので、積極的に予防接種を受けてほしい」という国家サイドの姿勢を国民に示すという意義もあるように思われる。このほか、厳格な運営がなされているとのことではあるが、苛酷緩和調整の規定が設けられていること（§63(5)）もそうした姿勢の表れのひとつとも受け止められる。いずれも連邦援護法においても同様の規定があるものであり、予防接種に限定されたものではないが、②にも関連するが、社会の目的のために個人が被る被害を救済する姿勢を広く示すことで、立法やそれに基づき講じられる措置に対する人々の安心感、信頼感にも資する条項と考えられる。

これらの特徴が明らかになる一方で、残念ながら予防接種被害救済に係る州政府の実務実態や、予防接種被害救済を受けながら医師に対して民法第823条の規定に基づき訴訟を行った事例の概要（どういった被害に基づき、結局患者はどういった給付等を誰から受け、医師はどのような負担を負

うことになったか等)や判例等まではあたることができなかった³²。また、被害救済に係る規定を実質的に定めている連邦援護法の条文や解釈の詳細についても、コメントールレベルにまで掘り下げた分析はできていない。これらの点は我が国の予防接種法改正を検討する際に重要な示唆を与える可能性があり、今後の研究に期待したい。

D. 健康危険情報

なし

E. 研究発表

なし

F. 知的所有権の取得状況

なし

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³² 医師は “gross negligence” があれば訴えられる, との, 「ノ」社三村弁護士からの情報 (B. 参照) はあるが, その実際の運用までは調査が及んでいない。

Arzneimittelgesetz vom 1.1.2004 bis
zum 31.12.2005" (English Abstract),
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Gesundheitsforsch - Gesundheitsschutz
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(参考) ドイツ感染症法条文 (英訳) (抜粋)

Section 2

Definition of terms

For the purpose of the Act,

11. vaccine injury

are the health-related and economic consequences of a health impairment due to vaccination the degree of which exceeds that of a normal post-vaccinal reaction; a vaccine injury is also present if agents capable of replication were used for vaccination and persons other than the person vaccinated were injured.

Section 6

Notifiable diseases

(1) The following shall be notified on a named-patient basis:

3. the suspicion of a health impairment the degree of which exceeds that of a normal postvaccinal reaction

Notifications pursuant to sentence 1 shall be made according to section 8 paragraph 1 nos. 1, 3 to 8, section 9 paragraph 1, 2, 3 sentence 1 or 3 or paragraph 4.

Section 8

Persons obliged to notify

(1) The following persons shall be obliged to notify:

1. in the case of section 6 the physician who has established the finding; in hospitals or other facilities providing in-patient care, the person responsible for notification shall be the chief physician

in addition to the physician who has established the finding, in hospitals with several independent departments, the chief physician in the department, and in hospitals which have no chief physician, the attending physician,

8. in the case of section 6 paragraph 1 the alternative medical practitioner.

(2) The obligation to notify shall not apply to personnel of the emergency medical service if the patient was taken to a physician-directed facility without delay. The obligation to notify shall apply to the persons stipulated in paragraph 1 nos. 5 to 7 only if a physician was not called in.

(3) The obligation to notify does not apply if the person obliged to notify has evidence before him/her that the notification has already been made and data other than those already notified were not recorded. Sentence 1 shall also apply to cases of illness already notified as suspect cases.

(4) Paragraph 1 no. 2 shall apply *mutatis mutandis* to persons who have the test for the detection of pathogens performed outside the territory covered by this Act.

(5) The person obliged to notify shall inform the health office immediately if a suspect case notified is not confirmed.

Section 9

Notification on a named-patient basis

(1) Notification on a named-patient basis by one of the persons mentioned in section 8

paragraph 1 nos. 1, 4 to 8 must contain the following information:

1. surname, forename of the patient
2. sex
3. day, month and year of birth
4. address of the main residence and, if not identical: address of the current abode
5. activity in facilities within the meaning of section 36 paragraph 1 or 2; activity within the meaning of section 42 paragraph 1 in case of acute gastro-enteritis, acute viral hepatitis, abdominal typhus/ paratyphoid fever and cholera
6. cared for in a community facility pursuant to section 33
7. diagnosis or suspected diagnosis
8. date of clinical presentation or date of diagnosis, if applicable date of death
9. likely source of infection
10. country in which the infection was presumably acquired; for tuberculosis country of birth and nationality
11. name, address and telephone number of the laboratory charged with diagnosing the pathogen
12. referral to a hospital or admission to a hospital or other institution providing in-patient care and discharge from the institution, if known to the person obliged to notify
13. any blood, organ or tissue donation within the preceding six months
14. name, address and telephone number of the notifier
15. for a notification pursuant to section 6 paragraph 1 no. 3 the information specified

in section 22 paragraph 2.

For the persons mentioned in section 8 paragraph 1 nos. 4 to 8, the obligation to notify is limited to the information available to them.

(3) Notification on a named-patient basis shall be made immediately to the health office responsible for the abode of the affected person, in the case of paragraph 2 the health office responsible for the submitting physician, not later than 24 hours after the detection of the case. Notification may not be delayed because of the absence of individual pieces of information. These shall be immediately supplied or corrected as they become available. Should the main residence or the habitual abode of the person affected lie in the jurisdiction of another health office, the health office notified shall immediately inform the health office responsible either for the person's main residence or, if the person has several places of residence, his/her habitual abode.

(4) The responsible pilot of an aircraft or the captain of a sea-going vessel shall notify the airport or port physician of the national places of destination and departure of any notifiable diseases detected on the way. The physicians in charge there shall pass the notification on to the health office responsible for the airport or port concerned.

(5) The health office may process and use the personal data notified only for the

purpose of executing its functions under this Act. Personal data shall be deleted, once their existence is no longer required for the health office to execute the functions within its remit; however, data pursuant to section 7 para 1 no. 21 shall be deleted after three years at the latest.

Section 11

Communications by the health office and the competent Land authority

(2) Any suspicion of a health impairment the degree of which exceeds that of a normal post-vaccinal reaction notified to the health office pursuant to section 6 paragraph 1 no. 3 and notification to the latter that a pharmaceutical product is suspected to be the source of the infection shall be immediately communicated by the health office to the competent Land authority and the higher federal authority responsible in this case pursuant to section 77 of the Drug Law. The communication shall contain all necessary information that can be established, such as name of the product, name or firm of the pharmaceutical entrepreneur and the batch number, for vaccinations additionally the date of vaccination and onset of illness. The patient notified shall be exclusively referred to by his/her date of birth, sex and the first letter of his/her first forename and the first letter of his/her first surname. The competent higher federal authority shall make the

communications available to the Robert Koch Institute for epidemiological evaluation within the space of one week. This shall not affect paragraph 1.

Section 20

Vaccination and other measures of specific prophylaxis

(1) The competent higher federal authority, the supreme health authorities of the Laender and the entities charged by them as well as the health offices inform the general public about the importance of vaccinations and other measures of specific prophylaxis against communicable diseases.

(2) A Standing Vaccination Commission shall be established at the Robert Koch Institute. The Commission adopts Rules of Procedure that are subject to the consent of the Federal Ministry for Health. The Commission issues recommendations on the conduct of vaccinations and other measures for the specific prophylaxis of communicable diseases and develops criteria for the distinction between a normal post-vaccinal reaction and a health impairment the degree of which exceeds that of a normal post-vaccinal reaction. The members of the Commission are appointed by the Federal Ministry for Health, in consultation with the supreme health authorities of the Laender. Representatives of the Federal Ministry for Health, the supreme health authorities of the Laender, the Robert Koch Institute

and the Paul Ehrlich Institute shall attend the sessions in an advisory capacity. The sessions may also be attended by representatives from other federal authorities. The recommendations of the commission shall be passed on by the Robert Koch Institute to the supreme health authorities of the Laender and subsequently published.

(3) The supreme health authorities of the Laender shall issue public recommendations for vaccinations or other measures of specific prophylaxis drafted on the basis of the respective recommendations of the Standing Vaccination Commission.

(4) The Federal Ministry for Health shall be empowered, after hearing the Standing Vaccination Commission and the central associations of the health insurance funds to determine by means of an ordinance without the consent of the Bundesrat that the costs for certain vaccinations are to be borne by the health insurance funds pursuant to section 3 chapter 3 of the Social Code Book V if the person is insured with a health insurance fund pursuant to section 4 of the Social Code Book V. The ordinance can also incorporate regulations on the recording and transmission of anonymised data about vaccinations performed.

(5) The supreme health authorities of the Laender can determine that the health offices conduct vaccinations or other measures of specific prophylaxis against

certain communicable diseases free of charge.

(6) The Federal Ministry for Health shall be empowered to determine by means of an ordinance with the consent of the Bundesrat that those segments of the population which are at risk have to undergo the vaccinations or other measures of specific prophylaxis if a communicable disease occurs that takes a severe clinical course or can be expected to take on the proportions of an epidemic. The basic constitutional right to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law) can be restricted in this respect. Any person required to undergo a vaccination under this ordinance who cannot be vaccinated without endangering his/her life or health and produces a medical certificate to that effect shall be exempted from the obligation to be vaccinated; this also applies to other measures of specific prophylaxis. Section 15 paragraph 2 shall apply *mutatis mutandis*.

(7) Where the Federal Ministry for Health does not avail itself of the powers conferred upon it by paragraph 6, the governments of the Laender shall be empowered to issue an ordinance pursuant to paragraph 6. The governments of the Laender may delegate the power to act to the supreme health authorities of the Land by means of an ordinance. The basic constitutional right to physical integrity (Article 2 paragraph 2 sentence 1 of the

Basic Law) can be limited in this respect.

Section 21

Vaccines

In the case of a vaccination stipulated by law, one required under the provisions of this Act, a vaccination recommended to the general public by the supreme health authority of the Land or a vaccination pursuant to section 17 paragraph 4 of the Act on Soldiers (*Soldatengesetz*), vaccines containing micro-organisms which can be excreted by the vaccinated person and taken up by others, may be employed. The basic constitutional right to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law) shall be limited in this respect.

Section 22

Vaccination card

(1) The vaccinating physician shall enter each vaccination immediately into a vaccination card pursuant to paragraph 2 or, should the latter not be presented, shall issue a certificate of vaccination. The vaccinating physician shall enter the contents of the certificate of vaccination into the vaccination card upon request. In his absence, the health office shall make the entry pursuant to sentence 2.

(2) The vaccination card or the vaccination certificate shall contain the following information on each vaccination:

1. date of vaccination
2. name and batch number of the vaccine

3. name of the disease vaccinated against
4. name and address of the vaccinating physician and
5. signature of the vaccinating physician or confirmation of the entry by the health office.

(3) The vaccination card shall contain, in an appropriate form, information on the proper conduct in the event of an unusual post-vaccinal reaction and on the claims that may arise from sections 60 to 64 if a vaccine injury were to occur, as well as the authorities at whose offices these claims can be put forward.

Section 33

Community facilities

Community facilities within the meaning of this Act are facilities in which predominantly infants, children and young people are cared for, particularly day nurseries, kindergartens, infant day-care centres, day-care centres for school-age children, schools or other educational facilities, homes, holiday camps and similar facilities.

Section 34

Health requirements, duties to co-operate, tasks of the health office

(10) The health offices and the community facilities mentioned in section 33 shall inform the persons cared for there or the persons having the care and custody of them about the importance of a complete and age-appropriate vaccine protection

that is sufficient according to the recommendations of the Standing Vaccination Commission and about the prevention of communicable diseases.

(11) As children are first enrolled in the first grade of a general school, the health office or the physician commissioned by it shall ascertain their vaccination status and transmit the aggregated data obtained that have been anonymised, to the Robert Koch Institute via the supreme health authority of the Land.

Section 35

Instruction of persons caring for children and young persons

Persons who exercise any teaching, educational, caring, supervisory or other regular activities in the community facilities mentioned in section 33 and have contact with the persons taken care of there, must be instructed by their employer about the health requirements and obligations to co-operate under section 34 before they first take up their duties and subsequently at a maximum interval of two years. The instruction shall be the subject of a record that shall be kept by the employer for a period of 3 years. Sentences 1 and 2 shall apply *mutatis mutandis* to civil service employers.

Section 60

Pension in the case of vaccine injuries and health impairments due to other

measures of specific prophylaxis

(1) Any person who has suffered a health impairment through a vaccination or another measure of specific prophylaxis that was

1. publicly recommended by a competent authority and administered within the sphere of its responsibility
2. prescribed on the basis of the present Act
3. prescribed by law or
4. administered on the basis of ordinances issued in the implementation of international health regulations, shall receive a pension upon request after the vaccination because of the vaccine injury within the meaning of section 2 no. 11, or following another measure to which the latter applies *mutatis mutandis*, in compensation for the health-related and economic consequences of the impairment, applying *mutatis mutandis* the provisions of the Federal War Victims' Compensation Act (*Bundesversorgungsgesetz*) unless the present Act provides otherwise. Sentence 1 no. 4 shall apply only to persons who were vaccinated for the purpose of re-entering the territory covered by this Act and whose residence or habitual abode is located in this territory or who had only left their residence or habitual abode temporarily for professional reasons or for training purposes, as well as their dependents who live with them in the

same household. The persons specified in section 10 of the Social Code Book V shall be considered dependents.

(2) A pension, within the meaning of paragraph 1, shall also be granted to German citizens who suffer a vaccine injury, outside of the territory covered by this Act, through a vaccination which would have been compulsory for a stay on the territory covered by this Act under the provisions of the Vaccination Law of 8 April 1874 in the consolidated version published in the Federal Law Gazette Part III, classification number 2126-5. The pension shall be granted only if the injured person

1. could not have been vaccinated on the territory covered by this Act,
2. was vaccinated by a physician and
3. had been living in the same household with either parent or a person who had care and custody of him/her at the time of the vaccination and if at such time said persons had been residing outside of the territory covered by this Act for professional reasons or for the purpose of vocational training and not only on a temporary basis.

(3) A pension within the meaning of paragraph 1 shall also be granted to persons who suffer a vaccine injury as a result of a smallpox vaccination outside of the territory covered by this Act administered in keeping with the provisions of the Vaccination Law or as the result of a smallpox vaccination which

was required by law or the administration of which was ordered on the basis of a law in the territories designated in section 1 paragraph 2 no. 3 of the Federal Act on Expelled Persons (*Bundesvertriebenengesetz*), in the former German Democratic Republic or in East Berlin unless compensation is being awarded on the basis of other legal provisions. Claims under sentence 1 may only be asserted by persons who had taken or take up permanent residence within the limits of the territory covered by this Act

1. as German citizens, by 8 May 1945,
2. as persons entitled under sections 1 to 4 of the Federal Act on Expelled Persons or section 1 of the Refugee Assistance Act (*Flüchtlingshilfegesetz*) in the version published on 15 May 1971 (Federal Law Gazette I, page 681) last amended by Article 24 of the Law of 26 August 1994 (Federal Law Gazette I, page 1014),
3. as spouses or descendants of repatriates within the meaning of section 7 paragraph 2 of the Federal Act on Expelled Persons in the version applying before 1 January 1993,
4. by way of family reunification pursuant to section 94 of the Federal Act on Expelled Persons.

(4) The surviving dependants of an injured person within the meaning of paragraphs 1 to 3 shall be awarded a pension upon request in application

mutatis mutandis of the provisions contained in the Federal War Victims' Compensation Act.

(5) A vaccine injury within the meaning of section 2 no. 11 shall also be deemed to be present in the case of a health impairment resulting from an accident which meets the prerequisites stipulated in section 1 paragraph 2 letters e or f or section 8a of the Federal War Victims' Compensation Act. Damage to a medical aid worn on the body, spectacles, contact lenses or dental prostheses resulting from an adverse post-vaccinal reaction within the meaning of paragraph 1 or an accident within the meaning of sentence 1, shall be equivalent to a vaccine injury within the meaning of sentence 1.

(6) Within the framework of pensions pursuant to paragraphs 1 to 5, the provisions of Chapter Two of the Social Code Book X on the protection of social data shall be applied.

Section 61

Recognition of health impairment

The probability of a causal link shall suffice for the recognition of a health impairment as a consequence of an injury within the meaning of section 60 paragraph 1 sentence 1. Should the only reason preventing this probability from being accepted be uncertainty in medical scientific circles about the cause of the detected condition, the health impairment may be recognized as the consequence of

an injury within the meaning of section 60 paragraph 1 sentence 1, with the consent of the supreme Land authority responsible for the pension scheme for war victims. Consent may be given generally. Recognition of a claim pursuant to sentences 1 and 2 and administrative acts based thereon, may be withdrawn with retroactive effect should it be established beyond doubt that the health impairment did not result from a vaccination or another measure of specific prophylaxis; benefits received do not have to be reimbursed.

Section 62

Therapy

Within the framework of his/her treatment, the injured person within the meaning of section 60 paragraphs 1 to 3 shall also be entitled to therapeutic pedagogical treatment as well as physiotherapeutic and kinesiotherapeutic exercises if these constitute a necessary part of the treatment.

Section 63

Concurrence of claims, application of provisions of the Federal War Victims' Compensation Act, transitory regulations for the reimbursement procedure to the health insurance funds

(1) Should claims arising from section 60 collide with claims from an injury within the meaning of section 1 of the Federal War Victims' Compensation Act, or other

laws which provide for a corresponding application of the Federal War Victims' Compensation Act, a uniform pension shall be fixed taking into consideration the reduction in the person's working capacity caused by all of the consequences of the injury.

(2) Should a pension claim pursuant to section 60 collide with a claim for compensation on the grounds of breach of official duty through negligence, the existence of the prerequisites stipulated under section 60 shall be without prejudice to the claim arising under Article 839 paragraph 1 of the Civil Code.

(3) Section 4 paragraph 1 no. 2 of the Social Code Book VII shall not apply in the case of vaccine injuries.

(4) Section 81a of the Federal War Victims' Compensation Act shall apply provided that the legal claim for compensation vis-à-vis third parties passes on to the Land obliged to grant the benefits under this Act.

(5) Sections 64 to 64d, 64f and 89 of the Federal War Victims' Compensation Act shall apply *mutatis mutandis* provided that the consent of the Federal Minister of Labour and Social Affairs is replaced by that of the supreme Land authority responsible for the pension scheme for war victims. Consent shall be granted in application *mutatis mutandis* of section 89 paragraph 2 of the Federal War Victims' Compensation Act in agreement with the supreme health authority of the Land.

(6) Section 20 of the Federal War Victims' Compensation Act shall apply provided that the number mentioned in paragraph 1 sentence 3 is replaced by the number of disabled persons and surviving dependents entitled to a pension pursuant to this Act compared to the number in the previous year, that in paragraph 1 sentence 4 the expenditure per pensioner of the health insurance funds as mentioned there is replaced by their national expenditure per member, that paragraph 2 sentence 1 applies to the supreme Land authority responsible for the pension scheme for war victims or an authority determined by it and that in paragraph 3 the number mentioned in sentence 1 is replaced by the figure 1.3 and sentences 2 to 4 do not apply.

(7) Any reimbursements for benefits provided by the health insurance funds prior to 1 January 1998 that have not been made by 1 January 1998 will be settled according to the reimbursement regulations applicable until that date.

(8) For the year 1998, the lump sum pursuant to section 20 of the Federal War Victims' Compensation Act will be assessed as follows: the annual average is calculated on the basis of the total amounts reimbursed by the Land to the health insurance funds pursuant to this Act in the years from 1995 to 1997, minus the amounts reimbursed for benefits in case of need for long-term care pursuant to section 11 paragraph 4 and section 12

paragraph 5 of the Federal War Victims' Compensation Act in the version applicable until 31 March 1995, and minus the amounts reimbursed pursuant to section 19 paragraph 4 of the Federal War Victims' Compensation Act in the version applicable until 31 December 1993.

Section 64

Competent authority for pensions

(1) The pension due according to sections 60 to 63 paragraph 1 shall be paid by the authorities responsible for the implementation of the Federal War Victims' Compensation Act. The local jurisdiction of said authorities shall be determined by means of an ordinance issued by the government of the Land liable to pay the pension (section 66 paragraph 2). The government of the Land shall be authorized to delegate the power to act to other authorities by means of an ordinance.

(2) The Law on Administrative Procedure with regard to the Pension Scheme for War Victims in the version published on 6 May 1976 (Federal Law Gazette I, p. 1169), last amended by the Law of 18 August 1980 (Federal Law Gazette I, p. 1469), with the exception of sections 3 and 4, the provisions of chapters one and three of the Social Code Book X, and the provisions contained in the Social Court Law on Preliminary Proceedings shall apply.

(3) Paragraph 2 shall not apply in so far as the pension comprises the granting of benefits which correspond to those awarded by virtue of war victims' relief pursuant to sections 25 to 27j of the Federal War Victims' Compensation Act.

Section 65

Compensation for official measures

(1) In so far as a measure pursuant to sections 16 and 17 causes the destruction of, damage to or otherwise a reduction in the value of objects or any pecuniary prejudice other than an insignificant one, compensation shall be paid in cash; however, no compensation shall be paid to any person whose objects are contaminated with or suspected of being contaminated with pathogens or pests which are presumed to be carriers of such pathogens. Section 254 of the Civil Code shall apply *mutatis mutandis*.

(2) The amount of compensation payable pursuant to paragraph 1, shall depend on the usual value of the object if the latter is destroyed; if it is damaged or its value otherwise diminished, the compensation payable shall depend on the amount of the reduction in the usual value. Should it prove possible to redress this reduction in value, compensation shall depend on the expenditure needed to achieve this. Compensation may not exceed the usual value which the object would have had, had it not been damaged or its value otherwise reduced. In determining the

usual value, the state of the object and all other circumstances which determine the latter's value at the time when the measure was implemented, shall be decisive. Compensation for any other than insignificant pecuniary prejudices may not place the affected person in a better financial position than he/she would be in had the measure not been implemented. Expenditure incurred as a result of the measure shall be reimbursed.

Section 66

Entity liable to pay

(1) Liable to grant compensation pursuant to section 56 is that Land in which the prohibition has been issued, in the cases provided for in section 34 paragraphs 1 to 3 and section 42, the Land in which the prohibited activity was engaged in. Liable to grant compensation pursuant to section 65 is the Land in which the injury has been caused.

(2) A pension due as a result of a vaccine injury pursuant to sections 60 to 63 shall be payable

1. in the cases provided for in section 60 paragraph 1 by the Land in which the injury has been caused,

2. in the cases provided for in section 60 paragraph 2

a) by the Land in which the injured person has his/her residence or habitual abode, at the time when the injury occurs, on the territory covered by this Act,

b) by the Land in which the injured person

had his/her last residence or habitual abode if no residence or habitual abode exists on the territory covered by this Act at the time when the injury occurs,

c) in the case of injured minors, by the Land in which the parent or the person having the care and custody of the injured minor, with whom the latter lives in a common household, has his/her residence or habitual abode on the territory covered by this Act or, in the event that such a residence or habitual abode does not exist, the Land in which the person had his/her most recent residence or habitual abode, if the prerequisites applicable to residences, contained in letter a or b, are not fulfilled, 3. in the cases provided for in section 60 paragraph 3, by the Land in which the injured person has established or establishes his/her residence or habitual abode for the first time upon the territory covered by this Act.

(3) In the cases provided for in section 63 paragraph 1 the costs generated by the supervention of additional injury, shall be paid by the provider of benefits who is responsible for paying the pension due as a result of the additional injury.

Section 67

Attachment

(1) The compensation to be paid pursuant to section 56 paragraph 2 sentences 2 and 3 may be attached according to the currently valid provisions on earned income contained in the Code of Civil

Procedure.

(2) The transfer, pledging and attachment of claims under sections 60, 62 and 63 paragraph 1 shall comply with the provisions of the Federal War Victims' Compensation Act.

Section 68

Recourse to the courts

(1) The normal recourse to the courts is possible in the event of disputes over claims to compensation pursuant to sections 56 and 65 and in the case of disputes over claims for reimbursement pursuant to section 56 paragraph 4 sentence 2, section 57 paragraph 1 sentence 2 and paragraph 2 sentence 3 as well as section 58 sentence 1.

(2) Recourse to the courts of social jurisdiction shall be possible for disputes under public law over matters arising from sections 60 to 63 paragraph 1. In so far as the Law on Social Courts contains special provisions governing the pension scheme for war victims, these shall also apply to disputes under sentence 1.

(3) Paragraph 2 shall not apply in so far as a pension is paid according to the provisions relating to war victims' relief pursuant to sections 25 to 27e of the Federal War Victims' Compensation Act. In this respect, recourse to the administrative courts shall be possible.

Section 69

Costs

(1) The costs for

1. the transmission of notification under sections 6 and 7,
 2. the carrying out of surveys pursuant to section 14 sentence 2,
 3. the measures pursuant to section 17 paragraph 1, also in conjunction with paragraph 3, in so far as they have been ordered by the competent authority and the need for the measures was not caused wilfully,
 4. examination and treatment pursuant to section 19 paragraph 2 no. 2,
 5. the measures pursuant to section 20 paragraph 5,
 6. the carrying out of investigations pursuant to sections 25 and 30,
 7. the carrying out of protective measures pursuant to sections 29 and 30,
 8. the X-ray examinations pursuant to section 36 paragraph 4 sentence 2
- shall be defrayed by public funds unless third parties are obliged to bear the costs by virtue of other legal regulations or by virtue of a contract. As for the rest, the liability to pay fees and the amount of such fees shall be governed by the law of the respective Land without prejudice to sections 18 and 38.

(2) It shall be within the purview of the Laender to determine who shall have to provide the public funds in question.

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分担研究報告書

アメリカ合衆国における予防接種の実際
—予防接種率の向上を維持するための制度設計に焦点をあてて—

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研究要旨

予防接種は疾病を社会全体の視点からみて抑止するという公衆衛生の問題としても、個々人の健康を守る上でも極めて重要かつ効果的なシステムであることが医療界では一般的な認識となっているが、国民一般においては、過去の集団接種の問題点や副作用を含めて予防接種をめぐる不幸な事象の影響もあり、必ずしも同様の認識が共有されているわけではない。しかし、今回の新型インフルエンザの発生を機に予防接種の有効性についての正確な認識や期待が社会に広まりつつあり、制度の抜本的な見直の契機となってきている。

そこで、その予防接種制度の抜本的な改革のために、米国をはじめとした諸外国の制度について調査を行い、その運用、背景等の詳細を明らかにするとともに、わが国における予防接種制度の見直しに資するような提案を行うことが、本研究の目的である。とりわけ、単に過去においてなされていたような強制的な制度に遡ることは現実的な選択肢となりがたい中で、現代社会一般に受容可能な制度構築に向け、予防接種の安全性の確保および効率的な運用のため諸外国においてなされている種々の対策について焦点をあてながら研究を行う。

それは、全般的には安全と考えられる予防接種においても少数ながら副作用によって重篤な被害が出る場合があり、現段階の科学的分析ではそのような副作用を完全に抑えることはできないレベルであり、しかも予防接種自体は、健康な人間とりわけ子供に対して行う予防的医療であることもあり、仮に個人レベルで接種を受けない場合でも即健康に悪影響が出ない場合も多いことから、そのような副作用を最小限にするためのモニタリング・システムおよび「その効率的な運用のフィードバックによる継続的な運用見直しを社会に対して透明性を保つ形で構築することが重要であると考えられるためである。そのような視点は今後の予防接種制度構築の上で必須の要素であり、本研究が寄与を目指す最大の部分でもある。

予防接種法の抜本的再検討においては、(1)予防接種法の対象となる疾病・ワクチンのあり方；(2)予防接種事業の適正な実施の確保；(3)予防接種に関する情報提供のあり方；(4)接種費用の負担のあり方；(5)予防接種に関する評価・検討組織のあり方；(6)ワクチンの研究開発の促進と生産基盤の確保のあり方、など6点が重要と考えられているが、本稿では2、3および5などに関係する予防接種の効率的な接種および記録、それに基づく安全性再確認の手段であるImmunization Registry（予防接種登録）制度（後にImmunization Information System：予防接種情報システム）に焦点をあて、報告する。