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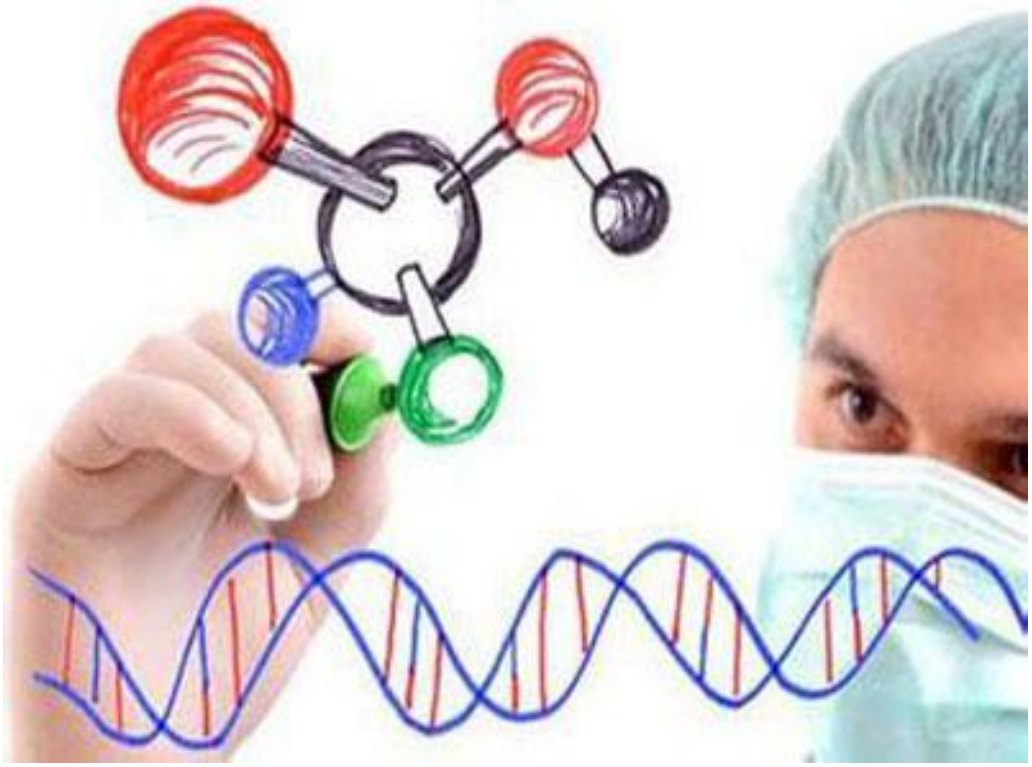
医药卫生法律资讯

Health Care Legal Newsletter

2016年8月　第18期



大成律师事务所
医药卫生法律研究团队

目录

Table of contents

Top of the document

一、 最新出台的医药法律法规
New Laws and Regulations on Medical Care Field

（一）食药监总局发布《关于修改〈药品经营质量管理规范〉的决定》
The Decision on Revising the Good Supply Practice for Pharmaceutical Products

1. 颁布详情 Enacted details

1) 颁布部门 Promulgated authority:The China Food and Drug Administration
2) 发布日期 Promulgation date: July20,2016
3) 生效日期 Effective date: July20,2016

2. 跟踪报道 Related content

2016 年 7 月 20 日，食药监总局发布《关于修改〈药品经营质量管理规范〉的决定》（下称《决定》），自公布之日施行。

《决定》将原规范第二十二条第二款修改为：“从事疫苗配送的，还应当配备 2 名以上专业技术人员专门负责疫苗质量管理和验收工作。专业技术人员应当具有预防医学、药学、微生物学或者医学等专业本科以上学历及中级以上专业技术职称，并有 3 年以上从事疫苗管理或者技术工作经历。”将第三十六条第二十一项修改为：“药品追溯的规定；”将第五十七条修改为：“企业应当建立能够符合经营全过程管理及质量控制要求的计算机系统，实现药品可追溯。”此外，《决定》还对第二条、第四十九条、第六十二条等作出修改。

The China Food and Drug Administration ("CFDA") has recently promulgated the Decision on Revising the Good Supply Practice for Pharmaceutical Products (the "Decision"), with effect as of the date of promulgation.

According to the Decision, Paragraph 2 of Article 22 of the original Good Supply Practice for Pharmaceutical Products is revised to read: "Enterprises engaged in vaccine distribution shall also allocate two or more professional technical personnel responsible for vaccine quality management and acceptance. The professional technical personnel shall have a bachelor's degree or above in preventive medicine, pharmacy, microbiology or medicine and professional technical title above intermediate level, and more than three-year experience in vaccine management or technical work." Item 21 of Article 36 is revised to read: "provisions on the traceability of pharmaceutical products;" and Article 57 is revised to read: "An enterprise shall set up the computer system meeting the requirements of management and quality control in the whole operation process, in a bid to achieve the traceability of drug quality." In addition, the Decision sets out the revisions to Articles 2, 49 and 62 and other articles.

3. 详情 Details：《关于修改〈药品经营质量管理规范〉的决定》全文

The Decision on Revising the Good Supply Practice for Pharmaceutical Products

Top of the document

（二）《网络食品安全违法行为查处办法》

The Measures for the Investigation and Punishment of Illegal Acts concerning Online Food Safety

1. 颁布详情 Enacted details

1) 颁布部门 Promulgated authority: the China Food and Drug Administration
2) 颁布日期 Promulgation date：July20,2016
3) 生效日期 Effective day：October1, 2016

2. 跟踪报道 Related content

2016年7月20日，食药监总局下发《网络食品安全违法行为查处办法》（下称《办法》），自2016年10月1日施行。

《办法》具体内容包括：一是强化平台和经营者义务；二是细化严重违法行为的具体情形；三是明确违法行为的管辖；四是强化调查处理职责；五是细化抽样程序；六是明确了责任约谈的情形；七是强化了法律责任。其中，《办法》明确了网络食品交易第三方平台提供者和通过自建网站交易的食品生产经营者备案、保障网络食品交易数据和资料可靠性、安全性以及记录保存交易信息等义务，并规定了网络食品交易第三方平台提供者建立登记审查等制度、建立入网食品生产经营者档案、检查经营行为、发现入网生产经营者严重违法行为时停止提供平台服务等义务。

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3. 详情 Details：《网络食品安全违法行为查处办法》全文

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Top of the document

二、重要法律解读

Interpretation on new and important law

新慈善法解读[1]

Interpretation of the new Charities Act

2016年3月16日，中华人民共和国第十二届全国人民代表大会第四次会议通过了《中华人民共和国慈善法》，此法自2016年9月1日起施行。此法的目的是为了保护慈善组织、捐赠人、志愿者、受益人等慈善活动参与者的合法权益。

该法共计12章112条，相比于1999年的《公益事业捐赠法》，无论是条文数量还是内容的丰富性，都有着显著的进步。值得注意的是，《公益事业捐赠法》与《慈善法》的内容虽然在很大程度上重合，但并未因《慈善法》而失效。现今新的慈善法马上就要开始施行，以下是对新的慈善法的简要解读。

1. 慈善法界定了慈善活动及其主体

本法所称慈善活动，是指自然人、法人和其他组织以捐赠财产或者提供服务等方式，自愿开展的下列公益活动：

(一)扶贫、济困；
(二)扶老、救孤、恤病、助残、优抚；
(三)救助自然灾害、事故灾难和公共卫生事件等突发事件造成的损害；
(四)促进教育、科学、文化、卫生、体育等事业的发展；
(五)防治污染和其他公害，保护和改善生态环境；
(六)符合本法规定的其他公益活动。

从此条可以看出，慈善活动的范围已被具体界定，同时慈善活动的主体为自然人、法人和其他组织。

2. 慈善法规定了慈善组织的设立及其组织形式

根据旧的《公益事业捐赠法》，慈善组织设立都是按照《基金会管理条例》和《社会团体登记管理条例》来进行规制；需“双重许可”，即慈善法人在得到主管机关的许可后，还必须经过专门的登记机构审批和登记。新的慈善法规定，慈善组织是经过登记的社会组织形式，依照慈善法有基金会、社会团体、社会服务机构等三种形式。新的慈善法仅仅强调登记，未涉及审批。今后慈善组织登记或申请认定的门槛或将降低，我国社会组织双重管理体制或将被打破，以慈善基金会等为财富保护传承模式的富人慈善将更为普遍。

3. “慈善募捐”－ 要求公开募捐需要具备相应资质，公开募捐必须履行法定义务

公开募捐的慈善组织必须拥有资质。募捐分公开募捐和非公开的定向募捐两类，对于公开募捐，只能由具有规定资质的慈善组织进行。依据慈善法的规定，个人不得公开募捐。

慈善法第二十六条规定，不具有公开募捐资格的慈善组织和个人基于慈善目的，可以与具有公开募

[1] 本文由北京大成（上海）律师事务所沈涛律师撰写。

Top of the document

捐资格的慈善组织合作，由该慈善组织开展公开募捐，募得款物由具有公开募捐资格的慈善组织管理。个人如果要公开募捐，可以通过慈善组织来做，这样依法募捐、有法可依。

4. 慈善法从捐赠人的角度规定了“慈善捐赠”及其权益

慈善捐赠财产可以是资金、实物、有价证券、股权、知识产权收益等有形或者无形财产。大额捐赠要通过慈善组织进行，以便享受国家税收优惠政策。如果不经由慈善组织进行捐赠，无法享受税收优惠。小额捐赠如果捐赠人没有享受税收优惠政策的要求，可以不通过慈善组织，直接向受益人捐赠。

对于数额较大的捐赠，签订捐赠协议是慈善组织的义务；并且，慈善组织接受捐赠，应当向捐赠人开具由财政部门统一监(印)制的捐赠票据。捐赠人有权约定受益人（受益人不得为捐赠人的利害关系人）与捐赠财产的用途，并享有知情权，如发现慈善组织滥用捐赠财产的，捐赠人有权要求其改正；拒不改正的，捐赠人可以向人民法院起诉。

5. 慈善法首次明确了慈善信托的重要地位

慈善信托是公益信托，指以实现社会慈善事业为目的，并以全社会或部分社会公众为受益人的信托。慈善信托首先不是理财。慈善信托在财富保护传承方面功能较大，它不仅借助信托独特的所有权和控制权相分离的法律架构，有效保善信托财产安全。

对于慈善信托，慈善法明确了慈善信托的备案制度，明确了受托人的范围，还明确了受托人、监察人的义务，并要求监察人发现受托人违反信托义务或者难以履行职责的，有权以自己的名义向人民法院提起诉讼。

6. 慈善法对慈善财产的去向和用途做了细致规定

慈善款必须专款专用。按照募捐方案或捐赠协议约定的用途使用；确需变更的，应当征得捐款人的同意。善款除进行慈善之外，为实现增值保值，在经过法定程序后，也可用于投资。慈善组织可与受益人约定善款用途，受益人未按照协议使用慈善财产或者有其他严重违反协议情形且拒不改正的，慈善组织有权解除协议并要求返还财产。

7. 慈善法保障志愿者服务和其相关责任归责原则

根据新的慈善法规定，志愿者服务保障包括实名登记、出具志愿者者记录证明、购买人身意外伤害保险等。志愿者活动的责任归责原则为慈善组织或者志愿者过错造成受益人、第三人损害的，慈善组织依法承担赔偿责任；损害是志愿者故意或者重大过失造成的，慈善组织可以向其追偿。

8. 慈善法规定了对信息公开的相关要求

新慈善法对信息管理的规定为“以公开为原则，以不公开为例外”。其中“以信息公开为原则”是指慈善组织的主管部门，慈善组织、慈善信托的受托人都负有信息公开义务。新慈善法对具体公开的范围都做了罗列。以“不公开为例外”是指：涉及国家秘密、个人隐私、商业秘密的不得公开；部分捐赠者或受益人不愿意暴露身份，慈善组织内部流程涉及商业秘密，可以不公开。

Top of the document

9. 新慈善法规定给予慈善组织税收优惠

新慈善法的第79条至83条规定了慈善组织及其取得的收入依法享有税收优惠。捐赠人、受益人也享有税收优惠，同时，股权、有价证券等财产形式的转让制定了优惠政策。

县级以上人民政府应当根据当地具体情况来制定相关优惠政策。

10. 慈善法细化了违法行为的“监督管理”

新慈善法规定慈善组织的主管部门为县级以上人民政府民政部门，并且要求其建立慈善组织及其负责人信用记录制度和慈善组织评估制度。同时，慈善行业组织也可对慈善组织进行管理。

11. 慈善法规定了“中华慈善日”

慈善法第7条规定，每年的9月5日为“中华慈善日”。

Top of the document

三、专业文章
Professional Articles

医药健康法与伦理道德[2]
Health Care Law & Ethics

Advancements in medical technologies and therapies have done much to extend life, but they have also generated an entirely new set of legal and ethical problems.
先进的医疗技术和诊疗办法可以延长人的寿命，但是也会引发一系列的法律和伦理大的问题.

“Despite the court's inability to compare a life afflicted by the most severe disability with death, there must be extreme cases in which the court is entitled to say: the life which this treatment would prolong would be so cruel as to be intolerable.” This opinion was posed by Lord Justice Taylor in his judgement of Re J (A Minor) and served as a valuable guide for Hedley J. in the search of Charlotte Wyatt’s fate. Charlotte was born premature in October 2003 and suffered severe and repeated respiratory failure. Advancements in medical technology made it possible for Charlotte to continue breathing as she fought for her survival in the early stages of her life. However, the case of Charlotte raised the controversial question as to whether her doctors could abstain from providing her with life-sustaining treatment should she stop breathing, for the quality of her life would be so poor. This essay will explore the legal and ethical dilemmas put forward by this case through a discussion of the principle of quality of life measured against the quantity of life and whether the courts are the best arbiters to make this judgement.

Charlotte Wyatt was born very prematurely and was beset by infection and breathing and brain functions which had steadily deteriorated. The damage was irreparable and required her to depend on a supply of oxygen. Charlotte was 11 months old at the time of the first action. She was blind, deaf and incapable of voluntary movements. Medical opinion was unanimous that she would be able to experience the pain of any future treatment. Prognosis for her survival was gloomy and lay between 25 per cent and 5 per cent. The hospital did not seek to withdraw her existing treatment but sought declaration that it would not be unlawful to abstain from ventilation should it be needed. Her doctors rendered ventilation “futile” for the fact it would only prolong Charlotte’s suffering where such aggressive treatment would not restore the quality of her life significantly. Her parents disagreed. Devout Christians, they believed Charlotte could respond to their affection and was not yet ready to die. The hospitals declaration was granted by Hedley J in 2004. It was concluded on the medical evidence that ventilation would only subject Charlotte to pain and distress and therefore it was not in her best interests for doctors ventilate her should she stop breathing. Hedley J. rendered that her life might well be “intolerable”. This, however, was not the end of Charlotte’s case. As her condition improved Charlotte’s parents wanted to ensure that the hospital would be required to do all that was possible keep her alive. Hedley J. once again affirmed his judgement concluding that Charlotte’s development was minimal and ventilation would not be in her best interests.

The prevailing factor in the diverse judicial reasoning of this case was intolerability: “is the treatment proposed likely to render the continued life of the child demonstrably awful?” Whilst treatment may be burdensome, it may be outweighed by the benefits the person may achieve from extended life. In Charlotte’s case the effect of the treatment itself influenced the decision of Hedley J.; the effects of the treatment only

[2] 北京大成（上海）律师事务所沈涛律师团队，本文以英国法律视角撰写。

Top of the document

generated intolerable suffering for Charlotte outweighing the possibility of a benefited continued life. There would be no benefit as a result of the treatment. The decision to withhold life-sustaining treatment where no further quality of life could conceivably accrue to the individual from existence may therefore be justifiable. On the balance of this it may be the opinion that to treat Charlotte and prolong her suffering would be "futile". In Re A Ward L.J. asserted that the sanctity of life allows each individual an equal right to life and that each life is worthwhile regardless of one's capacity to enjoy it. His Lordship rendered that "the question is always whether the treatment would be worthwhile, not whether the person's life would be worthwhile". In light of Hedley J.'s judgement, it can be seen that this principle was applied; the prevailing factor was the intolerability of treatment. The sad truth in Charlotte's case was definitively how and when she should die, and not whether she should be allowed to die.

In many instances where the courts intervene in the fate of an ill child, a family's grief is worsened by the anguish of court proceedings. But there has to be a means by which such dilemmas are resolved. Are there better arbiters than the courts to resolve such conflicts limiting the number of family tragedies which end in the court room? Dilemmas concerning the limits of life may be appropriately destined for the courts. One argument which could be made for this is the power of the courts authority; a judge can decide and effectively hold that a particular outcome must obtain. Hedley J. assuming responsibility for the questions of life and death insisted that "the court, as a publicly accountable body, is the proper repository of this responsibility rather than doctors and rather than the family". One of the dilemmas in this case was whether or not the court could be influenced by ethical values. Clinical Ethics Committees (CEC's) can be considered as this influence - but can they advise on an ethical approach alongside the courts within these dilemmas? It may be the opinion of some that the most suitable arbiters in deciding these cases would be a combination of the courts and CEC bodies. The CEC's can act to ensure that the courts take an approach of ethical appraisal within life or death cases.

The economic implications of neonatal care cannot be ignored. The cryptic spectre in all similar tragic dilemmas between the parents of a sick child and the professionals is resources. For parents there is fear that decisions in such cases are driven by economic implications that by treating their baby, resources may be unavailable to treat another baby. But how do we decide to allocate care where we have persons who require treatment for fatal illnesses and will have a more significant quality of life as a result of treatment? It is questionable as to whether or not it would be morally correct to provide Charlotte treatment that will not benefit the quality of her life at the expense of the resources which would benefit the quality and quantity of life another individual. Society has such radically diverse opinions on the nature of life and the moral status of life-sustaining treatment, that this question becomes so controversial.

The quality adjusted life-year (Qaly) is a measure of health outcomes which incorporates both the quality and quantity of an individual's life. The purpose of this measure is to condense the impact of treatment on a patient's life expectancy and the impact of the benefits to their quality of life in order to measure the health outcome to assist with the allocation of healthcare resources. However Qaly can be criticised. Again this draws on an ethical dilemma, questioning whether it is morally correct to allocate resources based on the measure of a human's quality of life against their quantity of life. Nuala Scarisbrick expressed her concerns over measuring the quality of life. She asserted that "doctors have no training in measuring 'quality of life, no one has" - yet we allowed the courts in the case of Charlotte to measure her 'quality of life'.

Disputes between parents and paediatricians about whether to continue to treat a seriously ill child are in no sense new in its kind. But the tragic dilemmas of Charlotte's case are novel in part because of the extensive publicity which surrounded the case in the media. The public interest which drew from Charlotte's case

Top of the document

expressed the sympathy felt for her and her family. For Hedley J. his decision was made in the best interests of "what can now be done to benefit Charlotte?" Further aggressive treatment would only be intolerable, serving no benefit to the quality of her life. The medical advice was that Charlotte should be allowed to die peacefully; Hedley J. asserted that her death would now only be "slightly advanced". Much has been said for the role of the courts in arbitrating these perennial conflicts between the parents of a sick child and the medical profession. The courts have the ultimate power of authority and to resort to judicial input may be the most pragmatic solution, but that does not necessarily mean that the decision of the courts is accepted. For some the solution is to combine the courts with CEC's to ensure that decisions can withstand ethical and legal scrutiny and remain justifiable. But what can be said for the ethical values of the court? To provide Charlotte the resources to only prolong her suffering at the expense of benefiting another's life could be considered unethical. Yet, this measure of ones quality of life against ones quantity of life becomes controversial; no individual possess the expertise to measure another humans 'quality of life'. A new dilemma is emerging that "obscures such value conflicts and, in which the translation of conflict into the disclosure of law, excludes moral debate rather than enable it to be addressed". Medical advancements, like that necessary to keep Charlotte alive, are regularly required, creating the need for an approach to tackle ethical dilemmas without the weight of personal, economic and religious values in deciding whether treatment is appropriate given the likely future quality of life.

Top of the document

四、大成医药卫生法律服务团队法律简报

Legal News on Health care legal service team

新闻简报：大成医药卫生法律团队为多家知名跨国医药公司的法务解读药品捐赠相关法规

Legal News:Interpretation of health laws and regulations related to drug donations for a number of well-known multinational pharmaceutical company's in-house legal

2016 年 7 月 13 日，大成上海办公室沈涛律师应恩弗拓企业管理（上海）有限公司 （简称“安拓”）的邀请，以主讲嘉宾的身份参与了题为“解读《药品捐赠相关法规》”的电话会议，参加此次电话会议的法务在线人员高达 48 人，安拓法律合规部会议主管 Dannie 主持了本次会议。 EverPro(安拓咨询)是一个专注于为企业法务经理人服务的会员制的咨讯和实践经验分享的专业平台。参加此次电话会议的法务人员包括强生（中国）投资有限公司、葛兰素史克（中国）投资有限公司、辉瑞制药有限公司、NBA 中国、赛诺菲（中国）投资有限公司上海分公司、第一三共（中国）投资有限公司、安斯泰来制药（中国）有限公司、阿科玛中国、百互润贸易(上海)有限公司 、礼来中国、上海新天地商业管理有限公司、波科国际医疗贸易（上海）有限公司、浙江海正药业股份有限公司、武田中国、赛默飞世尔科技(中国)有限公司、卡尔蔡司（上海）管理有限公司、住友制药（苏州）有限公司等知名跨国公司的法务合规人员。

沈涛律师此次分享涉及三大板块，第一板块主要围绕《捐赠药品进口管理规定》出台的法律背景及对药品的捐赠方主体、受赠方要求、相关进口备案程序进行详细分析，第二板块主要介绍《卫生计生单位接受公益事业捐赠管理办法（试行）》这一法律较旧法修改的亮点内容，第三板块和与会人员分享了新《慈善法》给广大医药企业带来革命性影响。其中穿插了大量的合规案例。 此次电话会议得到药企法务人员的积极相响应，沈涛律师详细解答了法务人员在公司合规实践中遇到的疑难问题，打通了医药捐赠合规理论与实践的隔阂，对跨国药企医药捐赠项目的合规具有十分重要的意义。

✓ **Please feel free to contact us if you have any further request.**
有任何进一步疑问敬请随时和我们团队联系。

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本期编辑：沈涛

Top of the document