Elements of pharmaceutical safety and quality from the 'short twentieth century' today

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Abstract
Given the sense of memory focused on the combination of the man-in the history of medicine and science of the profession, you start with hints indicative prior to the twentieth century and an evolutionary context of the entire premise of the 'short twentieth century' to carry out a survey to the current times on the main elements of safety and quality in the pharmaceutical world or in areas related to it, and more specifically, in scientific research and in industrial production, in institutions and in the profession, identifying the traits essential operational or addresses of evolution. The conclusion focuses on the potential global importance of projective scenario beginning of the third millennium, not apart from the magisterium and the pastoral care of the Church.

History

1843: abuse Friendly Godfrey**; 1853**: hypodermic needle**; 1937**: case of the elixir of sulfanilamide; **1948**: Birth of the World Health Organization**; 1956**: the case of thalidomide; **years 60/70**: Safety of packaging; **1975**: Millis Report; **1982**: Seal pharmaceutical warranty; **90s**: the first online pharmacy; **1996**, more than 2,500 deaths from fake drugs; **1997**: WHO International Conference on Developing Effective Communications in Pharmacovigilance; **1998**: Communication of the Executive Committee of the Union Pharmaceutical Grouping European GPUE on e-pharmacy; **1999**: Report on the analysis Worthen Millis, the birth of the online drugstore; intervention of U.S. President Bill Clinton on e-pharmacy; **2004**: the Ministry of Health standards for traceability of medicines; **2005**: Berlin Declaration on Pharmacovigilance of the International Society of Drug Bulletins (ISDB) Europe; **2006**: Charter approved by the Medicines FOFI; International Conference WHO / AIFA Combating Counterfeit Drugs; International Task Force IMPACT; **2007**: Resolution of the Council of Europe on good practice in the distribution of medicinal products by mail; Task Force IMPACT-Italy; **2008**: Global Forum on Pharmaceutical Anti Counterfeiting; traceability with 2D barcodes; **2013**: Operation 'Viagra home delivery'.

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e-pharmacy; 13. The problem of safety and quality of the drug in e-business; **14.** The e-business of counterfeit drug; **15.** The case of Viagra; **16.** Conclusions. Notes, References essential, Brief Profile of the author.

Greetings and thanks

A cordial greeting to the authorities, Gentlemen, Colleagues and heartfelt thanks to the organizers, particularly Rodolfo Taiani, for the invitation to this event, in a picturesque setting and a beautiful city that reminds me, forgive the personal digression emotional, wonderful summer vacation youth for over 10 years in Cavalese, Val di Fiemme, ranging in North and South Tyrol. I work for about 15 years of history of the Sovereign Order of Malta, its military events, religious and relations with the Holy See and the rulers of Europe. When I qualify in the historical institutional and academic environments, often I point to be an art historian care (in a ministerial body under protection), and sometimes I'm mentioning the AISF (unknown to most): Sometimes, though, some allude or explicitly show that beside the great story I also deal in history minimal. I do not hesitate, then, betraying a hint of frown about, and not just because I have a pharmacy in the mind and heart and is dear to me, as well as the Academy of History of Sanitary and Noble College Chemical and Pharmaceutical, in which I have the honor to be a member, even the Italian Academy of the History of Pharmacy. Today, in fact, the meaning of my communication is deliberately focused on a core value of the drug as a relationship between men and civilization; said, therefore, a history of human-disease-care and / or protection-prevention, in which art pharmaceutical industry remains important as in the past. Since then, Congress also in non-technical use more valences of study.

1. Introduction

With regard to the sense of memory pharmaceutical art, it is considered that it identifies many important social values and a result of technical and scientific disciplines (including biology, chemistry, medicine), having as its object the relationship between disease and organ living. With this in mind, the center of its meaning are the care and medicine (and, in recent times, the protection and prevention). The object of the history of pharmacy, therefore, is not only the profession but also the medicine, such as the relationship between men and civilization.
The history of sanitary arts is the discipline that studies the relationship between man and disease-care (and / or protection-prevention), in various countries also object the training of health professionals. In this context, the pharmacy profession continues to be important as in the past. The areas of the history of the drug, therefore, correspond to both the history of science and the history of the profession that the socio-economic and, currently, the main address is within the synthesis of these two perspectives.

2. Preamble

The industrial revolution, evolution and spread both technological and scientific computer revolution with the exponential availability of information and awareness of critical mass and capacity, the elevation and socio-economic welfare and the evolution of the concept of paradigm in health terms not more than the absence of illness and pain, but of well-being and prevention determine accessibility to good drug requiring extended, however, to the governance of public companies and adequate standards of quality control and protolli prevention and strengthening the contrast abuse and fraud, often with the active role of the pharmacist and institutions related to it.

3. Address of study

This study will identify some of the crucial phenomena of social change of attitude towards the drug, taking in evolutionary factors and critics of the turnaround in attention to the protection of health, tradottasi mainly in raising levels of control and quality .

4. Further reasons

Since this is a message to a conference is open to the general public ', to the layman, I wanted to take this opportunity to extend some values of the contents of the study targeting them to: 1. Strengthen the awareness of the degree of collective protections put in place by the entire chain of the drug and the institutions involved, with particular emphasis on the Institute of Pharmacy, 2. Increase the degree of self-protection in self-care and

collaboration of the social body in contrast to deviations dispensatory pharmaceutical companies. An overall action, therefore, oriented to feed through enough information and training as well as eminently education and prevention.

5. Introduction: indicative elements prior to the twentieth century

Much of the nineteenth century is characterized by the production and use of large quantities of drugs that, not infrequently, are due to events 'side' without any assumption of responsibility or awareness by the community, resulting in obvious and sometimes invasive distortions social . Around 1830, for example, in the town of Coventry is acquire weekly, in any form, about 38 liters of Friendly Godfrey, counter product made from opium widely used pediatric: this amount is equal to about 12,000 doses, or to a course of therapy for at least 3,000 children! In times not long, however, several checks and inquiries and begin to take action on various events most sensational and, already in 1843, is the same Friendly Godfrey to go to the fore in a spectacular example of the epidemic of child abuse: emerge, in fact, the Second Report of the Commission of Inquiry on Child Labour and Child, the testimony of a forensic pathologist who noted that only a pharmacist in Nottingham has prepared and sold in a year, as many as 3 tons of syrup, equal to more than 3 million doses. A public health research English in the nineteenth century, however, says that a pharmacy sells on average in a year in various pharmaceutical forms ... 90 kg of opium, from which they can be extracted about 9 kg of heroin!

Not to mention, then, of the discovery of the hypodermic needle by Wood in 1853, which also causes the spread of opioids in the mood, with the appearance of both positive and negative: the discovery of the effectiveness of the use by parenteral of morphine determines wide use in war to soothe the pain of the wounded soldiers in the military but appear the first cases of addiction in addition to those of opium smokers as, for example, in dens run by Chinese immigrants in America.

6. Social evolution of the attitude to the drug

6.1. The case of the Elixir Sulfonilamide

In 1937 a major event causes a revolution in the attitude towards American medicine: the death of 107 people in a few days if swallowed a cough syrup. After several attempts to laboratory, in fact, the Massengin and Co. of Bristol fails to produce an elixir Sulfonilamide (solution in propylene glycol sulfonamide with red dye and strawberry flavor) in less than two months that places on the market in the initial amount of 900 liters. But the elixir propylene glycol acts as a powerful poison rapidly toxic to the kidneys of the person who ingests causing terrible pain, coma and death agony with course average of less than 9 days. The Food and Drug Administration FDA has been informed of this by chance and immediately sends inspectors at the manufacturing company where they find that you have not done any testing on preventive medicine. The industry, however, did not violate laws because the testing is not mandatory and, contr'altare, nothing can be done in terms of legislative influence on the FDA itself, being still a small federal institution active only since 1906. The FDA, however, order the mandatory withdrawal of the product (over 1,300 packs), classified as lethal, the entire national territory. It is the first major operation in the history of the withdrawal of a drug from a national market: FDA inspectors and agents for days travel thousands of miles by plane, car and train across the country for the seizure of the product in pharmacies. The operation, however, is complicated because different pharmacies sell the elixir without registering it or giving recipes to prescribers: the agents, however, are able to control more than 20,000 prescriptions! At the same time, the Director of the Federal FDA Campbell personally follows the situation and accused the drugmaker of false designation showing that the elixir of sulfonamide product does not have alcohol as, instead, specified on the label. Finally, the mother of one of the young victims of the deadly elixir writes to President Roosevelt asking for a resolute action to prevent further incidents in the future: in 1938 the U.S. President signed a law reforming the Food and Drug Administration FDA, approved by Congress in just 6 months. From this point it is up to the FDA certification and testing of each drug companies are more accountable about what they produce and bring to market.

A further strengthen the foundations of public health, then, you have 7 April 1948 with the establishment, by 26 states including Italy, the World Health Organization (World Health Organization) that deals with permanently, through recommendations and directions , to prevent endemic diseases, reduce causes of mortality, promote social

and health care around the world and contribute to the fulfillment services to protect the health, especially in developing countries.

6.2. The case of Thalidomide

On 25 December 1956 there was a birth of child phocomelic, limbless developed because of a drug: thalidomide tranquilizer for pregnant women, then proved teratogenic. In 1962, when thousands of children are now born phocomelic, thalidomide was withdrawn from the market. The disaster is likely to push the Senators Estes Kefauver and Hubert Humphrey to initiate a review of the FDA and the previous act that regulates the marketing of drugs. The legislative act Kefauver-Harris requires pharmaceutical companies to produce not only evidence on the safety of their medications but also their effectiveness, using specific tests.

6.3 The cases of pharmaceutical packaging vulnerable

During the sixties of the twentieth century there is another crucial event in the history of medicine: about 11,000 children die every year from accidental overdose of aspirin pediatric (widespread: in 1950, is in the Guinness Book of Records as the world's best selling analgesic). The parents immediately blame the packaging of drugs: pharmaceutical companies, in fact, have started to market aspirin in plastic bottles, but a simple cap on a bottle does not stop many curious children who eat aspirin tablets mistaking them for candy. The U.S. federal government intervenes and provisions require child-resistant packaging. In 1970, in fact, Congress passes a decree on the safety of the packaging of toxic products that are intended for a child-resistant packaging for medicines and household products. In practice, however, this is easier said than done: we must make access difficult for children, but older people can open packages. The law, therefore, requires that at least 4 out of 5 children are not able to open the package in less than 10 minutes, while 9 out of 10 adults can open and close in a short time the package. The measures are successful with the screw cap. So in 1973, unintentional poisoning pediatric fell by 70%. Packing and packaging are radically modified to compensate two crucial human characteristics: curiosity and fragility. But twelve years later it was again forced to change the packaging of drugs in 1982, in fact, 7 people die in Chicago for taking the counter medication Tylenol and this raises strong concerns about the security of the entire sector counter drugs. It turns out, however, that the stocks of the medicine in a pharmacy have been corrected fraudulently with cyanide but, now, market analysis indicates that the incident affects the colossal manufacturer Johnson & Johnson with a hardness that profilarne a rapid reduction bankrupt. The prestigious pharmaceutical company, however, is quick to react and clear determination withdrawing as many as 31 million packages of the drug and, just a few weeks by the murders, announces the introduction of a new concept of packaging: the warranty seal, signaling element of any tampering and danger. In practice, the cap is wrapped in cellophane and the bottle has a metallic seal impossible to reseal when opened and, finally, the box is closed with glue. This system is revolutionary and becomes a reference for the entire industrial sector (1). The Tyleol, therefore, in over 20 years has the trust of the physicians and more than 100 million Americans.

7. New features professional pharmaceutical and qualitative evolution of the drug

7.1. Further developments of institutional address in favor of the consumer of drugs

In 1975 the Commission study on the prospects of the profession established by the American Association of Faculties of Pharmacy Pharmacist publish the document for the future, known as the Millis Report from the name of the President of the Commission, in which it is observed discontinuity between "generation of knowledge about drugs and application of new knowledge into clinical use, "and identifies the cause of the lack of connection between the industry, which makes exploration and production of drugs, and the government, which governs the use of drugs but not culturally oriented doctor. Pharmacists emerge as a third force in communication between the two, and the pharmacy is defined as "service delivery system using knowledge of drugs and their effects": the director of development of this force indicates the construction of the clinical pharmacist (2), addressed not to the drug but "the patient who uses it." The expectations towards the "clinical pharmacist" in more recent times known significant acceleration in 1999 and Dennis Worthen, Professor of the History of Pharmacy at the University of Cincinnati in Ohio, published an analysis of the ratio Millis in a preface mentions the controversial reactions to the report, a wide range between enthusiasm and skepticism, and uses this analogy: "imagine you ask yourself on the road, in the direction of distant mountains, and after the whole morning travel the mountains seem as distant as the time of departure, still glued horizon. The journey continues through the

afternoon, but the mountains do not come close to anything, one begins to ask when and if it ever comes. Eventually you stop and you turn back, but it turns out that we have strayed so it can no longer see the point of departure: the mountains are still far away, but the trip is well begun. "

7.2. Qualitative evolution of the production of medicines

The pharmaceutical industry for some time and with determination evolves continuously focusing on the strategic objectives of the Quality system and the overall sense that this term takes in each production sector for drugs fit for use: effective and suitable to ensure the most appropriate care possible. The objective of the modern pharmaceutical company, in short, is the production of high-quality medicines, virtually 'zero defects', empowering staff at all levels on the importance of the highest quality of both product and production process: the process parameters are ordinary be validated and critical, with significant variability from the effect on the quality of the finished product, must be accurately identified and monitored. These concepts are expressed both by ISO by Good Manufacturing Practices, basically references properly harmonized. In the logic of a Quality Management System of Quality Assurance and the importance of its decision-making task is enhanced while until a short time ago the role his own and the staff involved in the definition of Quality Management System was underestimated, it is not clear its impact on business final business: from what is evident is that there is no business without quality is that competition between companies is based precisely on the quality of the products.

8. Shares and addresses of recent drug safety supervision

Since many major milestones in this field in recent decades, I indicate some significant elements or Addresses from the recent public attention worldwide (3): 1) for drug safety monitoring, evaluation and communication are recognized activities associated with the public health with profound implications dependent on integrity and collective responsibility of each party to the proceedings: consumers, health professionals, researchers, universities, media, pharmaceutical industry, regulatory bodies, governments and international organizations. Standard highly scientific, ethical, professional and a moral code you believe should be the basis for such activities. The uncertainty inherent risks and benefits of drugs is required to be known and accounted for; decisions and actions based on this uncertainty is believed to be supported by scientific and clinical assessments, taking into account realities and social conditions, 2) defects Communication on the safety of medicines, at every social level, it is believed will lead to mistrust, misinformation and wrong acts harmful and give rise to situations in which the data of drug safety can be hidden, denied or ignored, and 3) there is awareness on the need to distinguish facts from speculation and assumptions and that the measures reflect the needs of stakeholders and the care they need. Such actions require systems and laws, national and international, to ensure a full and open exchange of information and valuation standards. These standards allow to estimate, explain, and weigh the risk-benefit of the general spirit of trust. 4) information on drug safety should be at the service of citizens' health and conducted in an ethical and effective, in terms of content, method, distinguishing between facts, assumptions and conclusions, admitting doubt and providing information according to the general needs and individual; 5) education on appropriate use of medications, including the interpretation of the safety data, it is considered essential for citizens, such as for patients and caregivers, and this requires special efforts and resources. The drug information directly to the public, in any form, it is believed can not be separated from being balanced with regard to the combination of risks and benefits; 6) Whereas any data requirements for evaluation and understanding of the risk-benefit should be available, it is believed that pressure on the parties involved in the communication, which prevent the achievement of this objective, should be identified and tackled; 7) every country needs a system with independent experts to ensure that the information on the safety of each drug are properly collected, impartially evaluated and made accessible to all. The system must be funded with adequate resources and independent. The exchange of data and assessments between countries must be encouraged and supported; 8) in the past have laid strong foundations for monitoring the safety of medicines, though sometimes in response to tragic events, while it is considered necessary in the future to ensure that the problems are readily identified and dealt with efficiently and that information and solutions are effectively and properly communicated. Thus, greater transparency based on legislation for freedom of information: from the moment the drug is marketed, regulatory authorities and pharmaceutical companies must make available all relevant data from pre-clinical and clinical trials, including animal studies. It is necessary that these data are publicly available to enable health workers and drug bulletins to establish the benefit / risk of treatment not only on the basis of the summary of product characteristics and the material provided by the industry. It is necessary that health professionals are informed

immediately of the new ADR. Should be disclosed potential conflicts of interest where such products exist; sharing data on pharmacovigilance through greater cooperation and integration between national and international bodies in the form, for example, communication network for pharmacovigilance. There should be standard methods to study the reactions to medications in order to implement a strategy of prevention, improved reporting and information gathering: ADR reporting in the post-marketing should be encouraged and actively involve all stakeholders (physicians, pharmacists, nurses , midwives, health professionals and patients). Pharmacovigilance should be part of the training of health personnel. Regulatory authorities and not (insurance companies) should initiate appropriate studies on the safety profile of particular drugs; better information for the patient and return information by the same: at the beginning of each treatment, patients should be informed about the potential risks and benefits of treatment. Independent information on drugs, clear and understandable, should be available to the patient wherever they are (including the hospital).

9. Aspects watch more closely related to the pharmacist

Patients often use drugs without prescription without consulting your doctor and, consequently, for many of them the pharmacist is the only health professional reference. The pharmacist is also in the position to identify problems related to multiple prescriptions from different specialists, who may not know or ignore requirements of others, to collect information not related to the doctor. However, it should be noted that many pharmacists are ill-prepared to report ADRs and, therefore, the ADR information reported to them by the patient to the pharmacist is often lost. Many hospital pharmacists also are not sufficiently integrated into the day of pharmacovigilance, although they have the best knowledge of the signals 'pharmaceuticals'. Pharmacists, then, should be educated on the assessment of risk / benefit, pharmacovigilance and ADR reporting and must embrace their growing responsibility to inform patients about the harms and benefits of medicinal products and in encouraging them to speak and report ADRs, including those related to the-counter drugs (OTC), complementary medicines and dietary supplements. On the other hand, finally, relies on the pharmacist the task of curbing the phenomenon of the gradual process of 'trivialization' that threatens to turn the drug into what is not, or a simple consumer product that is both "an objective threat to public health is the most deadly enemy of the pharmacy profession. 'Bribe' perception of public opinion, asserting almost exclusively values and economic contents, means in fact impoverish up to the de-legitimization (in terms of the role and function of guarantee) the figure of the pharmacist and the institute of pharmacy. Oppose the drift of 'normalization' which tends to make the drug a consumer product like any other, on which think only in terms of convenience, discounts and savings, is therefore to (...) the professional body (pharmaceutical) a 'urgency which to cope (4). "

10. The increase in fake drugs or counterfeit

Counterfeiting, as discussed above, do not spare even the world of medicine, indeed, from time immemorial. The phenomenon, however, assumes a very significant relief only since the last decades of the 'short twentieth century' and, moreover, the various elements symptomatic often initially not identified or are misinterpreted especially in their potential implications invasive and disruptive. For the World Health Organization WHO is counterfeit "a drug whose labeling is fraudulently prepared with misleading information about the content or origin of the product (...) by striking so much as brand-name drugs and generic ones (...) containing substances expectations , substances different from those expected, no active substance, insufficient amounts of the active substance or may be contained in a counterfeit packaging ". Distinction must be made, in particular, various types: perfect fake drugs, identical to the original but imported through illegal operations of the parallel market, fake drugs imperfect, with the right components, but not in exact amount (eg antibiotics under dosed, in many cases not optimal or therapeutically ineffective but inducers of phenomena of selection of resistant bacterial strains) and / or do not respect the requirements (for example in relation to maturity) or bioavailability or packaging (for example: the material of the containers and rules of sterility) , apparently spurious drugs, which do not contain the active ingredient and, therefore, unnecessary (far from harmless category: there are many deaths from respiratory diseases in African children treated with antibiotics without active ingredients and purchased at great cost); fake drugs criminals, that even contain harmful substances handled as authentic drugs, for example, the expired ones put back into circulation after relabel. No country in the world can claim to have never known the phenomenon of counterfeit drugs, recent estimates indicate that in Europe and the USA, in spite of strict controls, cases of counterfeiting incidents are a dozen a year with a clear upward trend while in some African states, 60% of counterfeit drugs would be (up to 70% of antimalarials), Brazil 30%, Europe 10%. In the United States, then, the

high cost of the drug, low contribution to the public pharmaceutical expenditure (only recently attenuated) and the economic crisis have caused the increase in the use of counterfeit products, often from Mexico, where it seems that 1/4 of medicines on the market is fake. Among a number of incidents, sometimes sensational tragedies, I will only mention a few of the century: in 1996 alone for the use of a fake vaccine in Nigeria during a meningitis outbreak killed 2,500 people in Haiti for use as unaware of a drug fake 72 children die after swallowing a syrup of paracetamol with propylene glycol excipient is not normal but the powerful and toxic antifreeze diethylene glycol. Counterfeiting of medicines, therefore, remains a crime whose gravity goes beyond the economic damage to the trademark constituting a massive public health problem (5) capable of generating in unsuspecting patients also serious loss of credibility of the entire system and dismay. But no one knows with certainty the overall size of the phenomenon: rough estimates, often based on unpublished reports indicate that approximately 10% of the drugs circulating in the world (in some countries, could exceed 50%) would be counterfeited, for a tour of 'annual turnover of tens of billions of dollars. The estimates, however, are subject to wide fluctuations in relation to the individual Nations and does not appear a real gravity for most European Union countries and, in particular, for Italy. In fact, the major manufacturers of drugs are illegal in China, India, Russia, Ukraine: the traffic would be managed by transnational organized crime (Russian, Chinese, Mexican and Colombian) and, it seems, there is evidence not to exclude a real threat of global mafias as a powerful sign for drug trafficking. Counterfeits usually affect both high consumption of drugs (eg antibiotics and vaccines, atorvastatin, sildenafil, tadalafil) is of limited use drugs (such as growth hormone paclitaxel or filgrastim) with the risk of insertion into the channels of pharmacy and hospital. In particular, 28% of the falsifications are antibiotics, steroids and hormones, 18%, 8% anti-allergic, anti-malarial 7%.

11. The fight against counterfeiting and falsification

Among the contrast mode counterfeiting include many resorts to technology such as, for example, by the European Commission, although this has not always unanimous. The proposals provide for new holographic seals unforgeable and lots centralized tracking systems, a ban on repackaging and other aspects less sophisticated with the favorable opinion of the majority of multinationals but sometimes with notable exceptions such as, for example, the U.S. giant Bristol Myers Squibb which, among 'else, do not like the idea of centralizing information on logistics and storage facilities, which are considered part of the business strategy and, therefore, sensitive matter and subject to the risk, actually not remote, of insider trading. The Association of European manufacturers of generic EGA, then, considered, among other things, the questionable underlying assumption, namely that there are marks that are not falsifiable and computer systems impregnable in the medium or long term, as even the counterfeiters can to bridge the technology gap and recalls, in this regard, the famous case of the hologram counterfeit Microsoft in 2003. For the EGA, then, the answer is the harmonization of controls and compliance with existing laws, what, however, shared by all. Another aspect that creates differences regarding the prohibition of repackaging of pharmaceutical products, extent, indeed, already advocated by the European producers EFPIA, as well as by the European Commission, and intuibilmente main tool of parallel hoards that price differentials between different Union countries often causing concerns the largest holdings. According to EFPIA, in fact, the prohibition of repackaging is the main weapon in the fight against counterfeiting in Europe while the trade association of importers, the European Association of Euro-Pharmaceutical Companies EAEPC, parallel imports constitutes the most additional security, since importers shall check the medication before the new packaging; EAEPC, in this regard, stresses that in 35 years it has been established a single case of penetration of the distribution circuit in parallel by a medicine counterfeit and suggests, finally, that the European Commission increases surveillance at EU borders and face with much greater completeness the chapter of virtual pharmacies.
In February 2006 in Rome at the International Conference on Combating Counterfeit Drugs, sponsored by WHO and AIFA (6) with support of the International Federation of Pharmaceutical Industries and FIIM German Government to identify principles, strategies and actions technological, political, legislative, financial and commercial aimed at combat counterfeit drugs (7), the WHO, as well as supporting the need for increased law enforcement measures taken (targatura, colorimetric assays, radio-frequency identification systems) and to push for tougher laws (8), launches the establishment of the Task international force IMPACT (International Medical Products Anti-Counterfeiting Task Force), composed of governmental and non for further enforcement actions.
On 7 May 2007, the Task Force active IMPACT-Italy, whose table sit AIFA experts, investigators NAS (Nucleo Commodities), experts in the Official Medicines Control Laboratory Institute of Health and the Ministry of Health. The group, in fact, "work already informally for over two years, and was born under the pressure of

international initiatives of the World Health Organization (WHO) and the Council of Europe." Among the activities already underway include "projects for the training of NAS and the standardization of the methods of investigation, the project for the development of analytical strategies for the detection of counterfeit drugs and a study of the drugs distributed through the network Internet (9) ". In Italy, also, are active several significant measures of protection and contrast, often implemented with the collaboration of the supply chain of the drug, including the Decree of 15 July 2004 the Ministry of Health for the traceability of drugs with a stamp of recognition helpful, as well as for epidemiologic evaluations to verify the authenticity of the product and of course by the pharmaceutical company on the whole national territory up to pharmacies, to local health authorities and hospitals. In addition, in the period 2000/2006 the only Carabinieri for the protection of health NAS have been able to carry out interception and seizure of more than one million packs of counterfeit medicines or non-compliant and quality from non-controlled networks. The Pharmaceutical Security Institute, then, reports that in 2007 there was a 24% increase in seizures of counterfeit drugs, with a value of approximately $ 3 billion in confiscated in 99 countries. Even the same pharmaceutical companies run for cover, such as Sanofi-Aventis which opened in September 2008 in Tours (Paris) its new central laboratory anti-counterfeiting, among other things, used for some time safety label not falsifiable post on product packaging at risk of counterfeiting, from January 2011 onwards, the company announces the introduction in all European countries, the new technology based on the use of traceability Datamatrix 2D barcodes with the " 'ultimate goal to ensure the traceability of each package along the entire supply chain, from the pharmacist to the ultimate consumer, the patient. "

12. The phenomenon of e-pharmacy

In the early nineties appear online pharmacies, sites for direct purchases of drugs then electronically delivered to your home to the buyer. In a few years the web pharmacies exceed 11,000 units, according to the FDA that, at the same time, it opens in its offices a center of investigation into the matter. Among the strengths of e-pharmacy there are convenience, privacy, affordability and variety while among the major points of dispute include invasion of privacy (with the inclusion in the network of personal data), lack of enforcement of good manufacturing-conservation- transportation and health care fraud (10); sites outside the law also allow the purchase of almost all non-prescription drugs (11). According to a report INCB (International Narcotics Control Board, UN agency), 90 percent of orders to sites about drugs with a prescription, often dangerous and inducers of addiction. Investigators and representatives of American and European health authorities, then, define the web pharmacies "dark corner", dark corner of the health market. In May 1998, the Executive Committee of the Pharmaceutical Grouping GPUE European Union, chaired by Giacomo Leopardi, addressed to the European Union Parliament worried a communication on electronic commerce of drugs, which reports that the e-pharmacy break all the Community directives on electronic commerce of drugs, exposing the serious risks to public health, because I am baffled intervention and counseling professional doctor and pharmacist. In addition, the GPUE and the Standing Committee of European Doctors, noting the global dimensions of e-pharmacy, hope and urge States to work together and with the WHO to come to identify solutions also proposing, in the short term, fines providers rei to host online pharmacies. In the same year the centenary drugstore chain wallgreen Co. of Illinois in the United States derives from the e-service pharmacy with home delivery over $ 6 million (12). In early 1999, then, can be traced back to the birth of the pharmacies in the network organized as a phenomenon (13) and significant (14) are opened the first drugstore online (cvs.com, planetrx, dragstore.com), strongly sites supported by advertising, with vast assortment of goods and directed to broad sections of the population who, if he has medical knowledge, they can click on the button corresponding to the disease or disorder appear to see a list of corresponding drugs that can be ordered and delivered to your home . Some sites also sell only to customers residing abroad for not responding to its own laws, and other sites collect orders and money and then disappearing or close clone credit cards or drugs directly. At this time there are no instruments of repression because the Internet makes it elusive: the site is domiciled, for example, in Korea or Vietnam, but the drugs are shipped from countries in which certain substances circulate more freely. To block all regulation is needed planetary internet or an endless series of bilateral agreements between the governments of the various countries involved. During this period, a survey of Comscore, an important center for monitoring, show that visitors to the web pharmacies are growing at a rate between 15 and 36% per annum. On 28 December 1999 the President of the United States Bill Clinton to intervene directly on e-pharmacy, offering new and stricter penalties for illegal online pharmacies: between measures include fines ranging from $ 500,000 for each violation of the rules, realization of public education campaigns about the dangers inherent in the purchase of drugs online, granting greater powers and resources to

the FDA to increase control over the network. But on the other side, take sides consumer groups who accuse the FDA wanted to do, using fear as a tool of deterrence, a "financial war against the American people," that is a policy of saving the super profits of Big Pharma, are now collectively referred to as the large multinational health. These associations lie on their side even governors of states and mayors of large cities. At the end of 2006 is now the most remarkable phenomenon of surfing the Internet for the collection of information on health (their own or family members and relatives) or on drugs, so that in Italy, even if the coefficient of computerization is not among the highest in the world , a global network world wide web is the primary source of health information for over 20 million internet: as much as 78% of Italians, amounting to 15.6 million people, navigating to a year to find medical information, for an average of 4 different diseases (15). The web, in any case, it seems the Italians the main source of help in the search for medical information: in fact, we turn to the net in 66% of cases (13.5 million people), therefore, much more than we face with: doctor (54%), pharmacists (53%), friends or family (34%), books or newspapers (31%), TV (25%), radio (6%). To do prefer to search for news online is the very nature of the medium "that allows frequent and easy" to get information, click on the page of a search engine in 72% of cases in specific portals (51%), the sites of pharmaceutical companies (28%) or those of information (22%). The Italian sites the best known and used are still relatively few and generalists in the face of the need for 80% of Internet users access a deeper understanding of specific issues.

13. The problem of safety and quality of the drug in e-business

At least in the pioneering phase of e-pharmacy, serious risks to public health are made by ignoring good conservation in the transport of drugs, delegated to professionals who handle them like the common commodity, while authorities and lawmakers, facing for obvious reasons of public health protection, do not opt for the contrast of the market, but for the raising of attention in vigilance and rigor in the regulation. Thus, for example, in the Old Continent September 5, 2007 the Council of Europe dismisses Resolution Res AP 2007/2 on good practice in the field of distribution of medicinal products by mail, to protect patient safety and quality of medicines distributed. In this modern Italian distance selling (via internet, mail order, etc.). Drug is not covered and can not, however, be regarded as permissible. In addition, Article 34 of the new Code of Ethics of the pharmacist, as well as under the old Article 25 expressly prohibits the sale of medicines through the internet. The Federal Council, in fact, tried to give a direction consistent with safety of citizens: an address because, unlike bodies of the Union, it does not legislate but recommended. In its resolution, the Council of Europe indicates that the Governments of the United States "to take all the necessary tools to ensure the safety of the sale of medicines by mail order, to protect patient safety and quality of medicines distributed." The focus is mainly on certain aspects: the distribution systems and the related liability, information and advice to be given to patients, the notification to the patient and by the patient, side effects, interactions, warnings, of recalls or quality defects of medicinal products sold by mail order, and the exclusion, by mail order of medicines particularly delicate; management requirements in the sale by mail order of medicines with a prescription. In general, the document emphasizes the need to not release the sale through pharmacies virtual (ie, dedicated websites) from pharmacies physically present in the territory, as the direct relationship is deemed necessary above all "as far as the council to the patient. " Neither the virtual pharmacy pharmacists should be free, as it states that "the sale of medicinal products by mail should only be performed by persons lawfully authorized" in European countries that are precisely pharmacists. The patients, the resolution says, "should receive advice through electronic means or by telephone. Should be maintained at acceptable levels of control on treatment (eg verification of dose, drug interactions, contraindications), as provided by the rules imposed by the national authority. " The mail order of medicines subject to prescription status, then, should take place under the responsibility of a pharmacist and upon presentation of a prescription, also sent by email, if authenticity of documented (what, at that time, not without difficulty of having to, for example, at least to use a system of electronic signature is not falsifiable). Finally, not all medicines could be dispensed in this way: "the drugs classified as narcotic drugs should a priori be excluded from the possibility of selling. Drugs that, even when properly packed, present potential risks to humans or the environment associated with the sale by mail, and those for which the due date is very close to the packing date, should not be sold for Match. "

14. The e-business of counterfeit drug

According to the U.S. Food and Drug Administration FDA trafficking of counterfeit drugs exploits with huge e-commerce using the results of a few thousand online drugstores. Although drug counterfeiting prerogative of

organized crime, should, however, consider that it is the active participation of people with professional experience in the production and distribution of drugs: this is not required to cause to be wary of an entire profession, has to take note, with dismay, the crisis of values that pervades the stakeholders involved in this crime (16). Nell'assise world experts in the fight against drug counterfeiting, Global Forum on Pharmaceutical Anti Counterfeiting of June 2008 in Washington (USA), one of the most alarming data that emerge from the work there is the estimate that the vast majority of drugs sold on- line, 62%, is somehow forged or fails to comply with the required standards and are an increasing number of fraud with drugs for chronic and serious diseases (including cardiovascular disease from those respiratory and psychiatric). Furthermore, the study 'Counterfeiting Superhighway' ('counterfeiting superhighway') presented by the European Alliance for Access to Safe Medicines (EAASM), sheds light on other practices potentially devastating during the survey of 100 online pharmacies, the 30 researchers ordering prescription drugs, among the most common and found that virtually all orders are processed in fact illegally without requiring any prescription, in addition, only 38% of the products received is a medicine 'genuine' and brand while in the other cases, 16% of products is illegal in the European Union and 33% did not package leaflet and, again, 95.6% of the online pharmacies operating illegally monitored by the study, 94% of websites do not need a pharmacist with title and verifiable identity. But even the researchers are particularly impressed to find that the anticoagulant clopidogrel would be sold online in many cases along with gift packs of sildenafil or counterfeit products that imitate this medicine, although it is now known that anyone who is being treated for serious problems heart should be under close medical supervision, especially when taking other medicines for other conditions as in erectile dysfunction.

15. The case of Viagra

In the growing phenomenon of e-commerce, there are pharmaceutical demand products, including the 'blue pill' for erectile dysfunction: In a survey of Pfizer-Global Security, carried out in 2011 on 22 websites (found by engines search by keyword 'buy Viagra'), 80% sell counterfeit pills containing only 30-35% (or a maximum of 50%) of the active ingredient sildenafil citrate. Consequently, the company Pfizer in May 2013 runs for cover launching in the U.S. the operation 'Viagra home delivery' (home delivery): purchase Viagra online with a regular order of a physician, using a reliable platform and its guaranteed by Pfizer, in collaboration with the chain Cvs / pharmacy that manages the sales site, with the first three tablets of the drug in homage to the first purchase and 30% discount on the second. The stated aim is to stop the illegal sale of the numerous counterfeit versions of the drug, which only records 24 million a year in research as a keyword in the search engines. But, as noted in the statements of a company spokesperson, there is also the intention to extend this method of selling other products. It is not excluded that others will follow this example by offering the ability to purchase prescription drugs most counterfeited and healing the lack of online sales channels guaranteed: according to the National Association Boards of Pharmacy today only 3% of virtual pharmacies is legal.

17. Conclusions

Looking back over the events of aspects of the history of the drug, among the highest synthesis of the progress made by humanity, it is understandably pervaded by consolation but also places on guard against casual attitudes in the application to it by those who do not consider, or undervalues the unavoidable difficulties and the inevitable risks associated with its production, management and use. From the history of drugs, yet, it is not difficult to draw the lesson that science and technology are real beneficial and unite men although it is always a risk of weakening the identity of certain derogate from the ancient and golden rules of 'right' and the 'middle' (also realizable in the abuse of medicinal products for motivation of a psychic rather than therapeutic need).
Pharmaceutical science and art, in addition, in the context in which they operate are inseparable from the ethical consequences of what is done: these human activities par excellence (can heal or hurt) imply the involvement in ethical debate with the rest of society, even ob wrong neck (17). "
While still seems to be just around the corner, therefore, hope that the voice of the pharmacy profession can still be clearly heard in the next few millennia, the memory of time is enriched by an avalanche of new unique insights from whose formidable applications and implications are hopefully, far from scientism proving the uselessness of God and the promises of eternal life on this Earth, or delusion of omnipotence while in the comparison between human and existential philosophies and practices alternative, that humanity will always remain dignified and the responsibility of each of the duty to live in freedom and spiritual awareness of their uniqueness.

God created the world as a lush garden, full of trees, bubbling springs, and meadows dotted with flowers. There he laid the men and women admonishing them: "At every commit wickedness that I will drop a grain of sand in this vast oasis of the world." But men and women, indifferent and frivolous, they ask: "What is it ever a few grains of sand in such a vast expanse of green?". And they live so fatuous and vain, small and great injustices perpetrated cheerfully. They do not realize that, every fault of their own, the Creator continues to decline on the world dry the grains of sand. Born, so the deserts from year to year spread out in a death grip tightening the garden of the earth, amid the indifference of its inhabitants. And the Lord continues to say: "But why my favorite creatures are bent on ruining my creation with such lightness and superficiality?".
This old Arab parable is the symbolic portrayal of human history, precisely marked by indifference, by a sort of moral atony that makes the company and the same land a desolate steppe in which men and women are stirred into a frenzy and foolish (18).
What is happening, as stated by a famous American Baptist minister, now our technical and scientific power has exceeded our spiritual strength and we drove well missiles and evil men (19)?
Certainly in recent decades emerges, with drama, a crisis of identity and culture prevailing in the West, and certain contradictions and problems are also evident in the pharmacy profession. It is desirable to safeguard values and criteria from careful analysis and a deeper vision, as if they lack strong values is easy to fall into the drama of Icarus, son of Daedalus, "taken by the flight towards absolute freedom and heedless of the warning "closer to the sun tumbling falls to the ground," forgetting that the wings with which he had raised to the sky were of wax. " The violent fall and death "were the price he pays for his illusion." "The ancient fable has its perennially valid lesson. In life there are other illusions that we can not trust without risking disastrous consequences for their own existence and that of others (20). "
In any case, knowing that in history there is nothing to ensure that the great moral dilemmas can be solved without pain and bearing in mind that the meaning of the story lies in the men who make it, appears to agree with the hope that the future will judge us with the same indulgence and charity with which we must now consider men of the past.

Notes

(1) This smart solution is able to contain the crisis, but one aspect of the packaging will continue to contribute to environmental devastation, with the amount of plastic waste that creates, at least until the problem is not solved, just from another chemical sector industrial, with a discovery equal to that of oil: the biodegradable polymer of polylactic acid or PLA, a true hero of the global economy and the modern world.

(2) Who is the clinical pharmacist at this time is not clear and the Commission itself admits it is difficult to define and describes it thus: "The sixties saw a growing movement towards a concept of clinical pharmacy is not yet clearly defined (...). The term clinical pharmacy has been used for the first time by a group of pharmacists engaged in a drug information center in the research phase. Later it was used to name a serious variety of roles played by individual pharmacists, groups and institutions (...). At present you can only describe the area as a spectrum of activities (...). At one end of the spectrum is a pharmacist in a pharmacy open to the public this integrates the pharmacist dispensing the medication with frequent consultation and close communication with the patient, the notification shall include the strengthening of existing instructions given by the doctor on the administration, dose and timing , possible interactions with other drugs, with food, with alcohol; expectations of efficacy and toxicity. At the other end of the spectrum is the hospital pharmacist who follows the doctor on the ward and regularly participates in the prescription pharmaceutical industry, which oversees the patient's response to therapy, which records data on the use and effects of the drug, which participates actively in the formulation of therapeutic protocols and guidelines, providing drug information to doctors, nurses and other health professionals (...). Between these two extremes there are all those other forms that play a greater or lesser extent, the activities described. "

(3) See: Erice Declaration on communication and drug safety; International Conference on Developing Effective Communications in Pharmacovigilance (organized in 1997 by the World Health Organization-Drugs Monitoring Center of Uppsala; International School of Pharmacology, Center for Scientific Culture Ettore Majorana); Berlin Declaration on Pharmacovigilance (2005) of the International Society of Drug Bulletins (ISDB) Europe.

(4) 'Paper Drug', signed by the Italian Society of Pharmaceutical Sciences SISF and the Central Committee of the Federation of the Associations of Pharmacists Italian FOFI in 2006.

(5) AIFA, real drugs, fake drugs, Editorial, Bulletin of Drug Information, XIV n.3, Ministry of Health, 2007.

(6) Italy in recent years has strengthened its cooperation with international organizations: the Council of Europe, for example, had the vice-presidency of the group to control the counterfeiting of medicines (AIFA, "real drugs, fake drugs "Editorial, Bulletin of Drug Information, XIV No. 3, p. 97 - Ministry of Health, 2007).

(7) Statement of the Assistant Director-General Howard Zucker, WHO.

(8) Howard Zucker, "If the counterfeiting of drugs were assimilated to the crime of attempted murder, because of what it is, and the pains were consequential disporremmo of an effective deterrent to combat the phenomenon" (The Pharmacist, n.4, February 23, 2006, p.5).

(9) Italian medicines agency AIFA, ibid., P. 98.

(10) Raimondo Villano, Towards the Global Information Society, Chapter I, Sector Analysis of the main telematics applications, pp. 25-26, Chapter II, Sector Analysis of the technical problems of application and / or development of information technology, pp. 45, 63-64, Chapter III, Safety and cybercrime: technical, legal and regulatory, p. 85:113 Chapter IX, Social Impact, p. 169:176 - Rotary International District 2100 Italy - Eidos Editions, January 2000.

(11) A sensational case is that of the American journalist Christine Beherens of WWMT TV Micigan that fills defiantly the form of a virtual tour by entering the name Tom, profession pet cat, height 15 cm, weight 7 kg, l ' operation undergone castration in 1988: get the sending home the bottle of Viagra required! (Source: The Pharmacist, Drugs & Internet, Italpromo, no. 9 of 10 May 2001).

(12) According to the National Association of chain drug stores-NACD, organization of U.S. drugstore chains, total sales of drugs online in 1998 exceeded $ 102 billion with projection to 2004 of not less than 150 billion. All analysts agree that the growth of the pharmaceutical market grows proportionally its e-business.

(13) Phenomenon preceded by smaller sites mainly specialize in the sale of large quantities of a few products for niche markets, such as, for seniors, for sports, etc..

(14) According to an estimate by default widely drawn up by the Food and Drug Administration U.S. FDA, in the year two thousand there are more than 1,000 websites to e-pharmaceutical business.

(15) Ask the user profile that uses the Internet to research information about his health presented in Rome in 2007 by Millward Brown Elf on behalf of Google Italy, Italian holding company of the most important search engine worldwide, and medical publishing house scientific Edra in collaboration with the search engine on the issues of health and health care.

(16) Abs. Rimaneggaiato by: Ministry of Health, Information Bulletin of drugs, AIFA, year XII, n. 5-6.

(17) Abs. Altered by the thought of the Nobel Prize for Chemistry Roald Hoffmann in: Science and Philosophy - Epistemology, The Beauty of Chemistry; Sole 24 Ore: Sunday 7 january 2007, n. 6, p. 33.

(18) Cardinal Gianfranco Ravasi, secular breviary, 366 reflections day after day, Introduction, Mondadori, 2006.

(19) Martin Luther King Jr. (1929-1968).

(20) Benedict XVI, Address to the opening of the academic year 2006-07 at the Pontifical Lateran University, October 2006.

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