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IMPROVING PUBLIC HEALTH: BLENDING SCIENCE AND REGULATION. THE ROLE OF THE FEDERAL HEALTH OFFICE

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Mr. Chairman, Ladies and Gentlemen, let me start with congratulations to the 50th anniversary of the Istituto Superiore di Sanità. The Federal Health Office of the Federal Republic of Germany in our country has tasks partly similar, partly different to those of this Institute. We can learn from your experience and I am convinced that this symposium will contribute to a better understanding and to improved cooperation between national institutions.

To improve public health, any action and regulation in the medical field should be based on good science and sufficient empirical knowledge. However, in order to increase the benefit and diminish the risks, sometimes we have to act, even if we do not know all the details with scientific accuracy. So let us take a bird's eye view at some of our problems regarding the relationship between science and regulation, which is the key issue of my presentation, and let us try to ask a few questions, hoping that some of them are intelligent ones.

I will start with a few questions regarding those sciences dominating medical thinking and regulation today. There are a lot of problems inherent in the regulation process itself, and I will pick out a few of them. Is it really necessary to blend science and regulation, and what are the sensible questions in trying to do so? What are the possible scenarios for the future in this respect? My remarks are random personal reflections of a scientist working in the field of regulation. I certainly have more questions than answers. But we cannot get answers without asking penetrant, painful and sometimes also stupid questions. I thought that you might enjoy such questions perhaps more than a detailed description of the Federal Health Office, which can be obtained in print by our agency, containing its function, structure and history, which might be known to most of you at least partly. The tasks are those of the FDA and partly those of CDC in the US, it is comparable to the Rijksinstitut in the Netherlands and also to the Istituto Superiore di Sanità in Italy.

Questions regarding relevant tendencies in medical science

The main input to regulation in health care is coming from two sources: new knowledge and new scientific developments on the one side and new diseases on the other. If there are no new facts, there will be no need for new regulatory decisions, provided that we have a regulation system in a steady state and that perception of regulation in the public opinion has not changed recently.

1) If this is so and if the change in the landscape of diseases is slow and partly predictable, my first question is: will the coming medical, biological and technical breakthroughs be controllable in the strict sense that one can prevent changes in the essential characteristics of medical practice as well as in medical and social system? I am not too optimistic in this respect and my first answer would be: perhaps no. The pill has changed not only the practice of medicine but the sexual behaviour of mankind. In the moment when the principle of the product was known, the process of developing it and delivering it to a major part of the population was selfcontaining and nobody could really controll it in the strict sense that it could be stopped. We have learned to assess the medical risk fairly well after some decades. With other breakthroughs we might not be so lucky. What might happen if human reproduction is performed outside the human body in some countries in considerable proportion and over a longer time? What might happen if techniques to shape people and their behaviour in a desired way are developed further? I am not convinced that all incoming inventions in molecular biology, immunology, genetical engineering and biotechnology, especially if they are put together into systems, are controllable in a strict sense. Some of them might considerably change our way of thinking and our way of life as well as our way of regulation. Results of science will not generally be preventable and nobody can predict the spin–

off effects completely in advance. So regulation might be challenged by new inventions more than we are used to, so far.

2) Will the paradigma of toxicology, which is central to our present thinking, be diluted during the next decades? Will it split into thousand testing systems and in a wide variety of empirical concepts, so that toxicology results are even more conflicting? How long will the notion hold that there is no lower threshold if we have a carcinogenic substance in one or two species? I have no idea how such questions should be answered. But things might change in toxicology by introducing new testing systems and new concepts, as they changed in the machine tool industry by the introduction of computers and new applications.

3) To what extent will the paradigma of epidemiology influence our future thinking in medicine and regulation? It surely will have some permanent impact like the paradigma of toxicology. After all, it has always been wise to count and to weight. But counting eggs alone very seldom made a good hen and it remains open how accurate this could and should be done in epidemiology. So epidemiology alone might loose some of its appeal like toxicology alone. But what will be if we are in a position to link both better than today?

4) Will information science be a real help in making use of the information avalanche in biomedicine? We can store and sort and process any information very fast, but someone must read it, and it must be evaluated. The frame of reference for information is changing year by year. The expectation of real help from informatics has a certain appeal, but the esperience is not yet very convincing in practice. The technical possibilities are attractive, however.

5) What will be the contribution of medical sociology and health care systems research to our future thinking and action? Will they both remain interesting academic entertainments without much relevance to real action, or will they change our views and decisions? I cannot answer this question either.

6) Do we have a theory of risk assessment or regulation? We surely don't. We have laws and they are applied as properly as possible. We have some basic bricks for such theories and some people are thinking about them. But we do not have a valid theory for risk assessment or a theory for regulation. On the other hand: do we need a science of science in order to improve medicine and regulation? I do not think so. Humans always acted in a simple way and science and regulation are obviously possible without accepted metatheory. This does not mean that such metatheories are not highly interesting cultural endeavours and perhaps more.

Some problems concerning the regulatory process

There are many problems concerning the regulatory process and I ask only four questions:

1) How to deal with irreversible wrong decisions? There are wrong decisions in industry, in medicine and there are wrong decisions of regulatory agencies. Some of them are reversible. If a wrong decision is recognized as such, it can and sometimes will be reversed. But some of our decision will remain irreversible for ever, for instance if a substance with desirable characteristics is wrongly stopped during the development or from access to the market. We might never learn what benefits a substance has if it is no longer in use. If a drug is removed from the market by a company without empirical evidence because of public pressure, we might never know what the facts really are. How to deal with irreversible wrong decision in regulation is an open question.

2) How to deal with pressure from interested parties? Health care is not only a humanistic undertaking. It has to do with treating people, earning money and making professional carriers. There are strong interests from consumer groups, from industry and from professional people involved. These interests are partly magnified in the media. It is important to know the interests, their conflict potential and the possible line of consensus when making regulatory decisions. A flexible approach which is firmly rooted in the facts and in consumer protection is the general strategy, but how to deal with such pressure requires a different answer in different countries and in different situations.

3) How to control regulation and its cost–effectiveness? To control regulation, mainly by the budget which is allocated to the regulatory agencies, seems to be not sufficient. A new way could be to put together the financial losses and the financial benefits from regulation in a regulatory budget for certain areas or as a whole, in order to see them in perspective and compare such a regulatory budget with a corresponding risk/benefit budget. But not everything can be measured in money terms. The satisfaction of a population with the health care system as a whole and with the medical services is very difficult to assess and to tranform in terms of money.

4) How to get highly qualified people to work in regulatory agencies? People entering our agencies are not always the best ones from a professional point of view. Other carreers are more appealing. However, it is not only a question of how much you can pay. What can we do for the training of our coworkers? An exchange of younger professionals between various countries for some months would be one of the possibilities for training. If we do not succeed at least partly, in the task of training our coworkers well, we are bound to have more trouble in the future. The size and complexities of the

regulatory problems and of the agencies themselves are such that they cannot easily be handled and need training over a longer period.

How to blend science and regulation?

We surely cannot regulate in a meaningful and sensible way without science and empirical research. If we do not succeed in integrating science and regulation, regulating will become, step by step, a gambling, farther away from reality. It is desirable to have some highly qualified research in house, but for various reasons it is impossible to have such research in the necessary quality and quantity completely within our agencies. In order to increase our efficiency we have to use more intensively the expertise of the scientific community.

1) What are the ways in which this can be done? Appointing advisory groups of expert scientists, using public hearings, giving research grants, cooperating in research projects with other scientists and using ways of formal and informal cooperation with universities are all possible means. These and other ways could be further explored and cultivated.

2) What about the atmosphere in dealing with scientists? Good science is very rare and shy. It needs a certain environment including freedom of thought and freedom in expression. In order to get good science involved in regulation we must be very flexible, sensible and thoughtful. Mutual understanding and trust are very important. The simple using of scientists as an input without understanding them does generally not work.

3) What is the key problem in blending science and regulation? Experienced people. We need scientists and medical doctors who are willing and educated to get involved in this difficult task of regulation, finding again new compromises between the changing knowledge and the changing side-conditions. Such people are the key limiting factor and our most valuable treasure in improving public health by regulation.

4) What should the general mixture between science and regulation be? The scientific and empirical facts should drive and dominate the decisions and the regulatory rules should be the firm riverbed for the scientific waters. There is a delicate balance between the dominance of experts, the legal framework and the pressure of interest groups. This equilibrium is different in every individual case and in every country.

Scenarios for the future relationship between science and regulation

There are three scenarios of which I can think:

1) Science and technology might produce new inventions which also change our system of regulation. Science and technology drive the regulatory process anyway and if real biological breakthroughs are combined with more influence of scientists, regulation could become more difficult. Regulation could then be less stable than it is today, because science has conflicting results and even more conflicting interpretations.

2) On the other hand, regulation could become so tough that in fact new scientific developments are stopped to such an extent that innovation is only possible in a piecemeal manner. Using scientists as an input without really understanding the complicated facts, could make the situation worse. Regulation could then be more stable than it is today, but this is perhaps not so desirable.

3) A more fluctuating equilibrium could develop between the scientific innovation process and the regulatory process, between the way scientists think and the way regulators think. The public interest in our field is helpful for this scenario. It would mean that we can roughly keep the present equilibrium between science and regulation, however with wider fluctuations.

The role of the Federal Health Office

The Federal Health Office has a history of more than hundred years trying to blend science and regulation in our country. Our Institution started when Robert Koch detected the tuberculum bacillus, investigating a variety of infectious diseases at the Robert Koch-Institut. At the beginning of the century the laboratories for water and air pollution started their work at Berlin as well as the laboratories for food and its analysis. In 1952 the Federal Health Office was founded again by federal law. It comprises now seven institutes:

- the Robert Koch Institute;
- the Institute of Water, Soil and Air;
- the Max von Pattenkoferinstitute;
- the Institute of Social Medicine and Epidemiology;
- the Institute of Veterinary Medicine;
- the Institute of Radiation Hygiene;
- the Institute of Drugs.

The Federal Health Office has the task to do research in the health field, to advise the Federal Government and other public institutions on health care problems and it has to execute certain parts of regulatory law, which require medical expertise, for instance in drug regulation. These general tasks are specified in many activities and projects and there is no time to name them here.

In performing its tasks our Agency has been successful, when our scientists were working at least partly in the front of science. The Agency has been successful when it could think in advance. It has a

satisfactory record in trying to find solutions in protecting the consumer for instance in the drug field. Trying to learn from our history we have no reason to change our basic philosophy: blending science and regulation. We try to do this with caution, beeing aware of some of the complications.

There are more questions than answers. Blending science and regulation remains partly an art. This art is different in the context of the cultural differences. The problems and the questions are however similar all over the world.

It was therefore very timely that this symposium was organized by the Istituto Superiore di Sanità on the occasion of its 50th anniversary. A substantial part of the work of the next fifty years will be dominated by problems existing between science and regulation and by the solutions we find for some of the questions I have tried to ask.