INTRODUCTION

DR. SHELDON SEGAL*

In 1995, the Rockefeller Foundation sponsored a conference to look at public and private sector collaboration in the field of contraceptive research and development, and to make recommendations for reducing constraints and promoting this partnership. One recommendation of this conference was to convene a subsequent conference to review experiences in liability and litigation and to compare different solutions in laws and regulations in the United States, Europe, and other countries.

The proposed meeting was convened in October 1996, organized under the leadership of the New York University School of Law Arthur Garfield Hays Civil Liberties Program. Participants were from Europe and the United States and brought with them a wide range of experience and expertise. The participants included: trial lawyers from both the plaintiff's bar and defendant's bar; in-house corporate counsel of major European and United States corporations involved in product liability issues; professors of tort law from the United States, United Kingdom and Sweden; legislative assistants to United States Senators concerned with tort reform; and, the general counsel of the United States Food and Drug Administration (FDA).

Several discussion papers were distributed in advance and served as the basis of the conference agenda. These papers are presented in this special issue of the *N.Y.U. Review of Law & Social Change*. This introduction summarizes key points presented in the conference sessions.

SESSION ONE

THE AVAILABILITY OF CONTRACEPTIVE METHODS: WHAT ARE THE CONSTRAINTS?

There has been a great increase in contraceptive use over the past 35 years, in both developed and developing countries. Consequently, fertility has been declining steadily. In developing countries, the number of children a woman will have in her lifetime has decreased from more than 6 in the 1960s, to less than four today. Most industrialized countries are at, or even below, replacement levels of fertility.[1]

The preferred methods of contraception vary from country to country, but, throughout the world, contraception is practiced chiefly by women. It is widely recognized that American women have fewer contraceptive

* Distinguished Scientist at the Population Council, New York, NY.

1. Dr. Sheldon Segal, *Contraceptive Update*, 23 N.Y.U. REV. L. & SOC. CHANGE 3, Part I. (1998) [hereinafter Update].

choices than European women. One issue affecting American women's choices is the variety of contraceptive products that are commercially marketed in the United States. Additional factors affecting American women's choices are the cost of contraceptive products, delivery systems, insurance reimbursements and restrictive regulations.[2]

Comparing the effectiveness of methods actually used in the United States and those that are either not available at all, or available on a limited basis, highlights the disadvantage that American women have in contraceptive choice. One outcome is that a shockingly high number of women who seek abortions in the United States were using a contraceptive in the month in which they became pregnant. In the mid-1990s, half of all pregnancies in the United States occurred in couples who were using contraceptives during the month that the woman became pregnant, and about half of these pregnancies were terminated by abortion.[3]

There is no surer way to reduce the number of unplanned pregnancies and abortions in the United States, and throughout the world, than by improving the effectiveness of contraception. Yet, contraceptive research does not have high priority in the American pharmaceutical industry. Ordinarily, when the science is ripe and there is a market for a product, companies support research and development (R&D) and enter the market. But most major American companies are not supporting contraceptive R&D. Patents on ideas for contraceptive products that could be developed are not being pursued.

According to the FDA, there were 50 investigational new drugs active in 1996 in the field of contraceptive research. They include work on new oral hormonal contraceptives, new implantables, new injectables, new delivery systems for hormones (transdermal, vaginal rings), a new IUD, vaginal spermicides/microbicides, and various items covered by device or diagnostics regulations. Confidentiality requirements make it impossible to examine fully these sorties into new product development, but most appear to be variations on existing methods or initiatives of publicly supported research programs that have not identified commercial partners for full development and marketing activities. These activities have generated very few new contraceptive products.[4]

Consumer advocacy groups and the plaintiff's bar in the United States believe that the country's imputed litigious atmosphere, particularly with respect to contraceptive product liability, cannot be held responsible for

2. Sylvia A. Law, *Tort Liability & the Availability of Contraceptive Drugs and Devices in the United States*, 23 N.Y.U. REV. OF L. & SOC. CHANGE 3 (1998).

3. Update *supra* note 1.

4. The information in this paragraph is based on the personal knowledge of various participants in the Bellagio conference.

the failure of pharmaceutical companies to give higher priority to contraceptive development. Their view is, "it is not lawyers who drove contraceptives off the market but drug companies who put defective products on the market."[5] They point out that the major class action suit in this field involved a product (Dalkon Shield) that was, indeed, faulty and deserved to be driven from the market, as it was. These groups also believe that Norplant, the most recent target of a large legal assault, was rushed into the American market without adequate research, warning labels about side effects, or preparation of health care providers for its use.

The impact of litigation against contraceptive products, however, is more extensive than this viewpoint suggests. The Dalkon Shield judgment was followed by liability claims against the Copper T IUDs for which there was no scientific evidence of faulty design or any other basis for product liability claims. The cost of defense and the burden on the legal departments of the affected companies, G.D. Searle Co. and Ortho Pharmaceuticals, led them to withdraw their products. Wyeth-Ayerst has backed its denials of plaintiff's claims about its contraceptives with substantial scientific testimony, but despite the testimony, the litigation has affected sales in the United States. The negative publicity generated from these lawsuits has already caused one European Company (ThJramex) to withdraw from a joint development partnership for an implant contraceptive with a foundation-supported R&D program, South to South. In addition, Wyeth International has postponed introduction of Norplant into the French market, despite receiving regulatory agency conditional approval for its use in that country. Officers of publicly-supported contraceptive R&D programs report that, "in talking with companies active in the United States market, it is clear that the liability issue is the biggest roadblock for introduction of new methods or investment in the field of reproduction."[6]

SESSION TWO

CORPORATE DECISION-MAKING AND CONTRACEPTIVES

Corporations that are or could be involved in contraceptive R&D are not monolithic. The factors that go into making a decision are not necessarily the same for American and non-American companies, large and small companies, those already in the field of women's health products and those that are not. Different companies will put different weight on different factors. A large multinational corporation, for example, might be fairly uninterested in a product with a market potential of one hundred million United States dollars, but with risks of liability and political hassle. A

5. Law, *supra* note 4, at Part III.

6. The information in this paragraph is based on personal knowledge of Bellagio conference participants.

smaller company might be eager to put such a product on the market because of its profit-making potential.

Corporations do not view themselves as instruments of social change. They are in business to make money. If they can do good at the same time, that is fine, but doing good is not what drives corporate decision-making. Costs of product development are high, and a realistic potential for return on investment is essential. Such an investment is also looked at in terms of displaced opportunities for other types of R&D. An advocate of a product with potential return equal to that of a new contraceptive or other female health product is likely to prevail in the competition for a share of the research budget because products giving women greater reproductive choice often have a "rage factor" that make introduction of the product more costly. The "rage factor" is defined as the aggregate of complaints, harassment, and threats that may be elicited because a company is identified with a particular type of product. Boycott threats are no longer the extreme in the area of reproductive choice. Death threats to individual officials and terrorist bomb threats against factories have also become a reality for companies considering products in the realm of reproductive choice. No other cause elicits comparable rage response, even though there are other issues that prompt opposition to particular products.[7]

Liability is one of the many factors that contribute to contraceptive R&D decisions. Although it is often alleged to be the main issue, as mentioned earlier, this is impossible to prove. For example, in the United States, both the availability and cost of product liability insurance are factors in deciding to market products. For reasons that are not clear, insurance companies charge higher liability insurance premiums for contraceptive products. Most observers doubt that this is based on actuarial facts, but rather may be another example of how political or social considerations have an impact on business matters in the contraceptive field. An investigation of the current practices of insurance companies is needed to determine if, indeed, contraceptive products are being "red-lined" without a factual basis for the elevated premiums that are charged. A possible remedy to this problem would be federally-guaranteed insurance for contraceptive products that cannot find insurance at reasonable rates on the commercial market.

Another key issue that affects corporate decision-making about new contraceptive products is product mix. Although the conclusion can be debated, officials of large companies already in the contraceptive field believe that the market is mature and that new products would simply cannibalize existing products. Companies with a large share of the oral contraceptive

7. For Wyeth-Ayerst, for example, the protests of animal rights groups against the use of bodily fluids from horses for the preparation of Premarin is a bearable burden, considering that Premarin is the largest-selling prescription drug in the United States, and the envy of the entire industry.

market are particularly concerned about this point. However, this attitude fails to recognize the opportunity for more effective products, as illustrated earlier, and the potential for attracting contraceptive users from the large and growing portion of people, particularly in the United States, who select surgical sterilization fairly early in their reproductive years.

Considering all of the factors that affect corporate decision-making, it may be an oversimplification to conclude that "the liability issue is the biggest roadblock" to new contraceptive product development. Like the cost of insurance, it is one that can be factored into a realistic business plan for a potential product. Other less tangible factors, such as perceived impact on the corporate image, or the threat to corporate tranquillity are likely to remain as barriers to contraceptive development even if some means are found to allay the burden of liability exposure.

SESSION THREE

LITIGATION RULES AND CULTURE: EUROPE AND THE UNITED STATES

It generally is assumed that tort law, especially product liability and medical malpractice, in European countries is vastly different from American tort law, and that this accounts for the fact that the rates of litigation and the costs of liability in European countries are only a small fraction of what they are in the United States.

Legal scholars find that European tort doctrine is reasonably close to American doctrine and can account for no more than a limited part of the great differentials in tort lawsuits and costs. General features of the American legal system seem to be far more influential than actual differences in tort doctrine in explaining the enormous difference between the number and costs of product liability (and medical malpractice claims) in the United States and their number and cost in Western European countries.[8]

SESSION FOUR

EUROPEAN SOCIAL INSURANCE AS A MODEL FOR REFORM

The Swedish social insurance program and pharmaceutical insurance plan have served as models for insurance systems elsewhere in Europe. Free or subsidized health care is provided through county councils, and a national income insurance program provided by the government covers individuals who have lost income as the result of an injury. An individual who has incurred medical costs because of injury caused by a contraceptive drug or device is unlikely to litigate to recover these costs since costs are subsidized by the county councils.

The pharmaceutical insurance plan is part of a more general social system in which a government-controlled agency has the sole and exclusive

8. *See* Mildred, *supra* note 7, at Part V nn.68-9; Law, *supra* note 4, at Part II.

right to sell medications, both to the general public and to hospitals. The pharmaceutical companies underwrite an insurance plan to provide compensation (beyond medical costs) to patients who incur injury from a drug or device. It is a "no fault" insurance plan, meaning an injured party is not required to prove negligence to receive compensation. The pharmaceutical insurance plan is paid for by all Swedish manufacturers and importers of pharmaceutical products. Each company contributes to the premium in proportion to the volume of its business. Compensation for injuries is paid out of the fund.[9]

The United States has adopted no-fault liability insurance programs to deal with particular problems. The possibility of a no-fault liability program for injuries resulting from the use of contraceptives deserves serious consideration.[10]

SESSION FIVE

CONCLUSIONS AND RECOMMENDATIONS

The group assembled for the Bellagio Conference was selected to include a wide variety of perspectives and expertise. On some issues, particularly the need for broader public education and attention, the group reached broad consensus. On others, particularly with regard to changes in liability rules, some members of the group were strongly opposed to the majority's recommendations.

Inform the Public

Public interest groups concerned with women's health, reproductive rights, and other population issues should develop policies and plans to enhance public awareness of the need to develop better contraceptives and for better access to the contraceptives presently available. The public is ill-informed about the contraceptive gap, the schism between the extent of needs and the level of activity in this field.

Work with Manufacturers

Drug manufacturers and distributors need to be assured that women's health advocates will support their efforts to provide a broader and more affordable range of contraceptive products. They must also recognize that consumers are seeking safe and readily accessible products.

9. Lotta Westerhall, *Disbursement of Indemnity for Injuries Related to Reproductive Drugs and Devices: A Swedish Perspective*, 23 N.Y.U. REV. L. & SOC. CHANGE 3 (1998).

10. Janet Benshoof, *Protecting Consumers, Prodding Companies, and Preventing Conception: Can it All Happen? Toward a Model Act for No Fault Liability for Contraceptives*, 23 N.Y.U. REV. L. & SOC. CHANGE 3 (1998).

Manufacturer's Responsibility

Manufacturers and health care providers should give users of reproductive health products full information on the risks and benefits of their products, including comparisons with other products. Contraceptive package inserts should be made more understandable to users. A form signed by the user, indicating comprehension of the information in the package insert, should be included in the patient's record.

The Role of Liability

The history of liability claims in the United States against contraceptive products is one of the issues that discourages manufacturers from investing in discovery and development in this field. Other factors include the high cost of new drug development, the elevated cost of insurance for contraceptives, an unwillingness to cannibalize existing oral contraceptive markets, and the desire to avoid controversy that could disturb the corporate tranquillity.

Litigation Rules and Culture

General features of the American legal system have far more influence than actual differences in tort law in explaining the large disparity in the number and cost of product liability claims in the United States and in Europe. These differences pertain to issues such as the role of judges, how lawyers receive their compensation, and the use of expert scientific witnesses.

Liability History of Contraceptives

The liability history in the United States of pharmaceutical products and devices pertaining to women's health suggests that litigation rules and other factors encourage the initiation of claims against these products. However, it is also true that some of the targeted products did pose a threat to women's health and deserved to be removed from the market.

Patient and Pharmaceutical Insurance in Sweden

The universal health care insurance program in Sweden, in which "no fault" personal injury insurance covers all medical expenses, essentially removes claims of personal injury from pharmaceutical products or medical devices from tort law procedures. Injured parties are entitled to receive compensation for their injuries according to a prescribed schedule. The Swedish system does not provide for large payments for pain and suffering or for substantial punitive damages. The Swedish system has served as a model for several European countries. Such an approach to providing health care and handling claims of injury insures that an injured person can recover all medical costs incurred without being forced into litigation.

Recommended Changes in United States Products Liability Law FDA Compliance Defense

Congress, and/or the states, should adopt a regulatory compliance defense that would allow a defendant to avoid punitive damages in cases involving reproductive drugs and devices approved by the FDA. Cases involving claims against drugs and devices are often mass torts involving many plaintiffs. Defendants are adequately penalized and deterred by awards of compensatory damages. Punitive damages are unpredictable, and in cases of flagrant violators, the FDA has criminal enforcement authority. The risk of this defense is that it could impose undue burdens on the FDA as companies attempt to broaden the scope of their protection from liability by submitting new drug application (NDA) filings even more voluminous than those prepared today.

Protecting and Encouraging Suppliers of Biomaterials

Congress should prohibit imposition of tort liability on the suppliers of biomedical materials reproductive health devices, including contraceptives. A bill limiting liability of biomaterial providers was passed by the 104th Congress. While the President vetoed the bill, he indicated that he would have signed this provision with a few changes. Congress should also pass legislation providing incentives to organizations that supply biomaterials to researchers creating new reproductive health products.

Improving Scientific Evidence

Federal courts should conduct evidentiary hearings on the admissibility of expert witness testimony, whenever requested by a party. In addition, federal courts should be encouraged to appoint a panel of experts, pursuant to Rule 706, to make findings regarding scientific issues in appropriate cases. States should be encouraged to adopt similar rules. Authors of scientific studies who are subject to subpoenas should be compensated for their time as expert witnesses by the party subpoenaing them.

Punitive Damages

Congress and the states should pass laws requiring that punitive damages in mass tort cases should be set in one consolidated action, after liability has been determined. Alternatively, punitive damages should be eliminated in mass tort cases.

Congressional Strategy

Promoting these objectives requires a broad congressional strategy. It would be useful to have hearings on the availability of contraceptives. European efforts to increase the availability, research and development of contraceptives should be included in such hearings, as well as a description

of programs to encourage private/public sector cooperation. In addition, a model act should be developed, addressing issues of compensation and liability for contraceptive-related injuries, and to assure the availability of liability insurance for contraceptive products.

Other Legislative Initiatives

Separate legislative initiatives should be developed and promoted to provide increased government funding for contraceptive research in the private sector. Recipients of government-financed research grants should be given strong incentives to seek FDA approval for their discoveries and make products available to women in the United States and elsewhere.

Developing Countries

Efforts should be made to help appropriate authorities in developing countries understand the strengths and weaknesses of the legal systems of Europe and the United States with respect to contraceptive issues.