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The Bitter Pill

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Fundamentally new approaches to birth control—for example, a male pill, a once-a-month menses inducer, and an antifertility vaccine—cannot be realized before the next century, and then only if the virtual withdrawal of the pharmaceutical industry from this field can be reversed. Major changes in product liability would be the most significant incentive.

IN 1951, WHEN OUR RESEARCH GROUP IN MEXICO CITY accomplished the first synthesis of an oral contraceptive (1), Mexico had 28 million inhabitants (2); it now has 86 million and has risen to 11th rank among the most populous countries. Mexico City is the largest city in the world and by the turn of this century its population will probably equal that of the entire country in the year of the pill's first synthesis.

The population growth of Mexico after World War II is not unique. In 1923, the year of my birth, the world's population was 1.9 billion. On my 65th birthday, it had exceeded 5 billion and at the present growth rate will reach 8 billion on my 100th birthday (3). Today the populations of Europe and Africa are virtually identical, approximately 500 million each. In just 35 years—in spite of famine and disease—Africa's population will triple unless the acquired immunodeficiency syndrome (AIDS) epidemic interferes with conventional demographic predictions. Europe's population will stay essentially the same.

Yet this is not the bitter pill of my title, which refers to the fact that the United States is the only country other than Iran in which the birth control clock has been set backward during the past decade. The quality of birth control in the United States is not likely to change by the year 2000, with the consequent likelihood that there will be no significant reduction in the number (1.5 million) of abortions that now take place annually in the United States. Indeed, the contraceptive choices in the United States at the end of this century may be even more limited than they are now.

Introduction of Steroid Oral Contraceptives

Until the introduction of the birth control pill in the early 1960s, abortion (then illegal in all but a few countries) was virtually the only available method of birth control separated from coitus. In my opinion, it was this property of the pill and the privacy it offered a woman, rather than the pill's efficacy, that made its initial acceptance so rapid. By the end of that decade, the cumulative decisions of nearly 10 million American women had made the pill the most popular method of birth control.

Yet even now, almost three decades later, epidemiological reports regularly include the debate as to whether prolonged use of the pill

increases the risk of breast cancer (4). Many women will be discouraged to learn that a conclusive answer will not be available before the turn of this century, because the dosages of both the progestational and the estrogenic components of the pill have been progressively lowered since the middle 1970s. The same reservation also applies to some of the beneficial, noncontraceptive effects of the pill, such as protection from benign breast tumors and ovarian, as well as endometrial, cancers (5). Will the protection persist for women taking the lower dosage steroid regimens?

The introduction of the pill into medicine came at the best possible time, and also at the worst. It was a time, before the thalidomide tragedy, when new drugs were rapidly being introduced; pharmaceutical companies, the media, and the public proclaimed and accepted the benefits of the postwar chemotherapeutic revolution. Every problem, be it a medical one or a social one such as the population explosion, seemed amenable to a "technological fix." It also proved to be the worst of times, because the same decade saw three important movements concerned with central issues of contemporary society—women's role in society, environmental protectionism, and consumer advocacy—achieve their aims largely by depending on the unique character of the U.S. litigation system.

The early influential books of the modern feminist movement emphasized the urgent need for improved female contraception. Simone de Beauvoir's *The Second Sex* (6) stated explicitly, and Betty Friedan's *The Feminine Mystique* (7) implicitly, that a liberated woman must be in control of her own fertility. Probably most women will agree that the pill, more than any other single factor, contributed to that aim. But an informed and highly motivated group of women—primarily American and, by world standards, exceedingly affluent—while emphasizing their abhorrence at male domination, also strongly criticized the pill (8) and frequently did so claiming to speak for women all over the world. They were concerned when the first epidemiological studies documented some of the pill's less obvious side effects (9). Women, who earlier had objected to being used as human guinea pigs, now asked why the pill had not been tested more thoroughly.

An undercurrent of such feelings persists. Even in the latest edition (1984) of *Our Bodies, Ourselves*, produced by the Boston Women's Health Book Collective, one can find it remarked that "the Food and Drug Administration [FDA] approved the pill for marketing in 1960 without adequate testing or study. . . . The pill became a gigantic experiment: within two years about 1.2 million American women used it. . ." (10, p. 237). Such large-scale, post-marketing "experiments" are unavoidable, however, and occur with every vaccine and drug to which a person will be exposed for long periods of time. Only medicines used to treat acute conditions and

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used over short time intervals can be effectively screened for most side effects during the pre-marketing, clinical test phase. With regard to the question of why it took so long to lower the initial high dosages of the progestational and estrogenic ingredients, it must be remembered that abortion was completely illegal at that time; experimenting with lower dosages might well have led to higher failure rates for which no alternative could be offered to the women on whom the new dosages were tested.

Retrenchment of Pharmaceutical Industry

When in 1970 I wrote *Birth Control After 1984*, I pointed out (11) that unless major and largely unpopular changes in public policy were instituted, birth control in 1984 would not differ much from that which existed in 1970. I emphasized that our increasing knowledge of human reproduction and of actual as well as potential side effects, along with women's concern about safety and risk aversion (shared by most of contemporary American society), made it necessary to plan on a 12- to 20-year development period for any new chemical contraceptive agent. At that time, there were 13 major pharmaceutical companies (9 of them in the United States) that conducted research and development (R&D) in contraception; by 1987, the number had dropped to four (only one of them in the United States). Today none of the active progestational and estrogenic ingredients of the pill is manufactured in the United States.

The withdrawal of the large U.S. pharmaceutical companies from contraception R&D (12) has had three major causes. The first was the stringent animal toxicology tests (7 years in beagles and 10 years in monkeys) demanded in 1969 by the FDA (13) in response to concerns about the long-term effects of steroid contraceptives. These requirements were not modified (14) until 20 years later as a result of overwhelming evidence presented by foreign regulatory agencies and the World Health Organization (WHO) (15) about the futility of such special "overkill" mandates. Second, the impact of the congressional "Nelson Hearings" (16) conducted between January and March of 1970 was exacerbated by the commentary of self-interest groups and further sensationalized by the press, thus giving the contraception field an extremely poor image. The fact that the pharmaceutical industry chose not to testify before Senator Gaylord Nelson's committee, and the subsequent disaster of the Dalkon Shield intrauterine device (IUD), only aggravated the hostility (17).

The third blow, and in the end the most devastating, has been the changes in the litigious character of our society during the past two decades, especially where drugs and medical practice are concerned. Unquestionably, the fear of litigation had a salutary impact on some practitioners and manufacturers in medicine in general and on birth control in particular. The Dalkon Shield is a prime example of a case in which litigation was essential. At the same time, contemporary tort law, with respect to legal liability, has altered medical practice for the worse. In the case of contraceptives, litigious practices have been extreme. In 1986, for instance, the Ortho Pharmaceutical Company lost a \$5,151,030 judgment in Georgia because its spermicide Ortho-Gynol, used by a woman while she was unknowingly pregnant, was alleged to be the cause of her baby's birth defects (18)—a possibility that is not consistent with current epidemiological evidence (19). And although in most malpractice and product-liability cases (for example, that of asbestos) the plaintiff recovers no more than one-third of the financial judgment, the remainder being consumed by the legal community (20), such litigation has added an enormous financial burden to precisely that segment of the population that the legal system was designed to protect, the consumer.

The impact of litigation on the pill is especially instructive.

Indisputably, some women have been physically harmed by the pill, and it is reasonable for society to compensate them in one way or another. Even though few pill suits that have gone to trial have been won by the plaintiffs, the legal defense cost for the drug and insurance companies has escalated to such an extent, especially because of liberalized discovery rules permitting plaintiffs' attorneys to demand tens of thousands of documents, that out-of-court settlement of such litigation is often cheaper than defending it in court. The Office of Technology Assessment (OTA) in its 1982 report (21) stated that liability costs in the oral contraception field were higher than for any other drug category. These legal costs are in the end paid for by the millions of women who benefit from the pill and who would probably object greatly if they were returned to the narrow contraceptive options of pre-World War II days. The cost of a monthly regimen of the pill has increased nearly tenfold in the United States during the past dozen years, even though most pills now on the U.S. market have been "off patent" for many years. Fear of litigation and unavailability of insurance has eliminated market competition: until 1988, no generic versions of the pill were available, and even the ones that have appeared recently cover only a fraction of the market (22) and are, in any event, manufactured by the producers of the proprietary formulations.

Pill Use in the United States

No new active ingredients have appeared in the pills sold in the United States since the 1960s. By contrast, three new ones (desogestrel, norgestimate, and gestodene) were introduced in Europe in the 1980s (23). The leading European manufacturer of the most advanced pill has so far not introduced its product (desogestrel) in the United States—in part because of potential liability exposures (24). Yet this product has one of the lowest dosages of all pills and, moreover, has an improved metabolic profile compared to the other progestational steroids currently available to women in the United States (25).

The negative publicity of the Nelson hearings (16) resulted in both justified and unjustified caution about the pill. Consumption dropped by over 20% to about 8 million women in the United States in the 1970s (although it continued to increase in Third World countries) but then started to rise again to the current all-time high of more than 13 million American consumers (26). The consensus now is that for healthy young women, the pill is the most effective contraceptive method and probably one of the safest. Women in their middle thirties or older were thought to be at increased risk in terms of cardiovascular complications, and the current pattern of use among such women in the United States reflects these beliefs, although the most recent epidemiological evidence concerning low-dose pills suggests that such risk applies only to heavy smokers (27). As a consequence of these concerns, and because of the lack of other effective alternatives, the incidence of sterilization has risen so sharply [in contrast to Western Europe (28)] that this essentially irreversible method now surpasses pill use among couples in the United States.

The attitude of feminist activists toward the pill has also changed. Although one can still find occasional anachronisms like the "born-again contraceptive fundamentalism" expressed (29) in 1984 by one of the early feminist writers, Germaine Greer (who indicates that she has no use for the pill and even denigrates the diaphragm in favor of coitus interruptus, the cervical cap, and condoms), the current position of most informed feminist spokeswomen toward contraception in general, and the pill in particular, reflects the realities of the 1980s. Like the vast majority of American women, they want for themselves and for their partners more choices, to suit the personal

and professional lifestyles of women working outside the home. They want full and up-to-date information on each method. In the case of the pill, this includes dissemination of the potential negative side effects as well as of the more recently discovered noncontraceptive benefits (5).

Women are now represented in substantial numbers in decision-making bodies dealing with contraception, such as the advisory committees of the FDA, the National Academy of Sciences, the National Institutes of Health (NIH), and the WHO. Also, whereas in the 1960s the overwhelming majority of American obstetricians and gynecologists were men, more than half of the residents and young practitioners in that subdiscipline are now women.

Yet just as women have entered every aspect of contraceptive development—from research and testing to delivery of the product—their choices are becoming more limited. This is primarily a consequence, again, of public, governmental, and media response to the complaints in the 1960s and 1970s of women who wanted a perfectly “safe” pill or other contraceptive. What do the professionals in contraceptive research have to offer in that regard?

The Current Climate

The fashionable area of human reproductive biology is now the study of infertility rather than contraception. The lessened prestige of the latter field is reflected by the paucity of new talent entering it. This is partly because relatively less money is now dedicated to contraception R&D than was the case 15 years ago (30). Not only have industrial expenditures virtually ceased, but the principal U.S. government funding agencies, the NIH and the Agency for International Development, because of mandates initiated under the Reagan Administration, are prevented from supporting many important areas of contraception research. To convert promising laboratory discoveries in animal reproduction into viable methods of human birth control is now so time-consuming, and so dependent on the participation of the pharmaceutical industry, that many scientists have turned to other fields because of the lack of material and societal support.

Another reason that scientific attention has turned away from contraception research is that, since the late 1960s, country after country in the developing world has recognized the problems of uncontrolled population growth and has started to implement birth control programs—some of them, such as the one in China, on a huge scale. Health professionals dealing with the delivery rather than the creation of contraceptive methods then decided that the emphasis in these countries should be placed on education, on the creation of the appropriate infrastructure, on the integration of contraception with maternal and child health care, and on the optimum use of existing methods (the pill, IUD, condom, injectable steroids, and sterilization) rather than on the search for new contraceptive methods.

This focus of Third World governments suggests how different is the perspective of women in the United States compared with that of women in poor countries. Here, IUDs have been rejected by many women, largely because of the defective Dalkon Shield. Makers of other IUDs—the Ortho Pharmaceutical Company with the original Lippes loop and G. D. Searle with the Copper Seven—have also withdrawn them without any pressure from the FDA. IUDs never did play a role, in fact, in the single most important birth control issue in the United States, teenage pregnancy, because the device is unsuited to young, nulliparous women. Yet in China at least 35 million women are estimated (31) to be wearing an IUD developed in the 1960s, thus making it the most prevalent contraceptive in that country. In Mexico, similarly, where the government

switched in 1974 from a laissez-faire pronatalist policy to an increasingly aggressive population control program, steroid contraceptives and IUDs are the key components of that program (32), followed by abortion.

In some Latin American countries, such as Brazil, IUDs are hardly used, and the pill continues to be the method of choice (33), whereas many Asian women prefer steroid injectables (33), which certain women's health groups in the United States continue to oppose. All this proves that couples all over the world need more choices. Strangely, three countries—the Soviet Union, Japan, and the United States—that might be leaders in the process suffer from a pronounced stagnation in the range of choices and the quality of birth control. Many people ignore the fact that incidence of abortion reflects the state of contraception. In the Soviet Union, the country with the highest per capita abortion rate in the world (34), the quality of birth control is exceedingly poor and the pill is essentially unavailable. Japan, the country with the third or fourth highest abortion rate, is the only industrialized country in which the pill is still not approved for contraceptive use (35). The United States, finally, has the highest teenage pregnancy and teenage abortion rate of any industrialized country (36).

I cite these three examples to show that improvements in contraceptive “hardware,” in addition to contraceptive “software” (for example, education, distribution, and health care), are likely to have an important effect on rich as well as poor countries. And this brings us back to the intuitive desire of most people in the United States for improved contraception. So what, again, do the professionals have to offer?

Prognosis for New Developments

The 1982 OTA report *Future Fertility Planning Technologies* (21) introduces a list of future contraceptive methods by saying that “between now and the end of this century, more than 20 new or significantly improved technologies for contraception are expected to become available” (21, p. 92). A similar article, published in 1986 under the title *The Next Contraceptive Revolution* (37), gives virtually the same list and cites a lack of financial support as the chief obstacle to its immediate realization.

My own view (38, 39) is much more pessimistic; regardless of the amount of money available, none of the truly revolutionary developments such as antifertility vaccines or a male pill have a chance of being used by the public in this century. The rest of the cited (37) contraceptive improvements, which include another vaginal spermicidal tablet, another copper IUD, and a cervical cap, although clearly useful in a public health and demographic context, are not new or revolutionary. A delivery system for steroid contraceptives, which replaces the daily ingestion of a tablet by steroid-loaded vaginal rings or subdermal implants, is no consolation to women wishing to abandon continuous exposure to a potent steroid hormone, especially when they learn that these supposed novel developments have been under way for nearly 20 years.

A Priority List of New Contraceptive Methods

What new contraceptive methods are needed and who would their principal beneficiaries be? The following list is short, yet ambitious, and arranged in an order of priority that I will justify.

1) *A new spermicide with antiviral properties.* The AIDS epidemic alone justifies putting this item on top of the list. Demonstrating antiviral activity, however, is not sufficient. A drug or formulation needs to be devised that will be effective under conditions of normal

use during coitus. The noncontraceptive benefit is likely to weigh heavily in any risk assessment and in FDA approval.

2) A "once-a-month" pill effective as a menses-inducer. Such a pill would have to be suitable for self-administration, in which case it could become the single most effective method for reducing the 40 to 50 million abortions performed annually throughout the world. In 1970 (11) I outlined the technical steps required to create such an agent and suggested why up to 17 years (the present lifetime of a U.S. patent) would be required for such work. An expenditure of \$100 to \$150 million now seems a conservative estimate for such a project.

Instead of the current pill, which is taken daily for most of all of each month, the menses-inducing pill would be taken by a woman only during those months when she had unprotected coitus. Theoretically, she would have to take only a single pill (containing a fairly short-lived and rapidly metabolized drug) on the day she expected her next menses. Instead of waiting to see whether she had missed her period, a woman would take the pill to induce menstrual flow at the expected time. Such a method would not be acceptable or suitable for every woman, but to many such a one-pill regimen would represent an enormous improvement: at a maximum, a woman would be taking 12 pills annually, rather than the present 250 or more. With such a menses-inducer women would not necessarily know whether they carried a fertilized egg. The single most important advantage of such a method is that the decision to contracept is made postcoitally.

Scientifically, there is little reason to doubt that such an agent could be created. The steroidal antiprogesterin mifepristone (RU-486), developed by research workers at Roussel-Uclaf in collaboration with an academic team headed by E. E. Baulieu (40), is the most significant research achievement of the 1980s in new practical fertility control. Current clinical data (41) show that the drug's effectiveness, especially when administered with a prostaglandin (42), is limited to initiating menstrual flow within 6 to 8 weeks after onset of the last menses; its administration mimics a spontaneous miscarriage. Because RU-486 is likely to disturb subsequent periods (43), induction of regular menses is probably not feasible with this particular drug. Anti-abortionists in the United States labeled RU-486 the "French death pill" and then threatened boycotts and other actions receiving front-page treatment in the *New York Times* (44) and other newspapers. The support that the Administration and some in Congress gave to these protesters is an indication of the present climate of fertility control in the United States. Neither Roussel-Uclaf nor a U.S. pharmaceutical company has so far applied for FDA approval of RU-486, even though hundreds of thousands of women in the United States might benefit from it.

3) A reliable ovulation predictor. For couples practicing "natural family planning" who are interested in more precise indicators of a "safe" interval than "natural" methods available now can give, it is much easier to detect (45) the time when ovulation has occurred (that is, the second half of the menstrual cycle) than to predict accurately the onset of ovulation. As human sperm has a fertile life span in the women's reproductive tract of up to 3 days, couples wishing to have unprotected intercourse during the first half of the menstrual cycle need to be able to predict the onset of ovulation by approximately 3 days beforehand. Such precise prediction is now technically feasible. What still remains to be done is to convert this into a financially realistic and operationally practical method for routine birth control. This approach to contraception would be equally attractive to prochoice and anti-abortionist groups. There is an additional educational bonus: for couples to depend on such a method, they would have to understand the timing of ovulation and other details of the menstrual cycle—information that I believe is widely lacking at present.

4) Easily reversible and reliable male sterilization. Millions of men, especially in the Northern Hemisphere, now undergo vasectomies, a sterilization procedure that is simpler and safer than tubal ligation in females. The overwhelming majority of these vasectomized men are already fathers; vasectomy would have to be guaranteed reversible before young men without children would opt for such a method of fertility control. The reversibility would have to be relatively simple and cheap. At present, vasectomy can only be reversed through expensive microsurgery (46). Even when normal sperm count is restored, immunological reactions frequently lead to infertile sperm. In the absence of virtually guaranteed restoration of fertility, presumably on the basis of epidemiological studies covering a minimum of two decades, the prospects for widespread dependence on vasectomy reversals are small, whereas the opportunities for malpractice litigation seem limitless.

5) A male contraceptive pill. I give this alternative a lower priority only because of its long development time. In 1970, I documented (11) the technical reasons why developing a male pill would take longer—probably on the order of 20 years—than work on a new female pill, such as a menses-inducer. Long-term assurance of safety, that has been insisted on by women for the female pill, is only available through large, long-term epidemiological studies. Safety may be more difficult to establish for men than for women, primarily because of the longer fertile lifetime of men.

6) Antifertility vaccine. In principle, this would be the most revolutionary development; it would radically change our perception of human fertility if teenage males or females, or both, were vaccinated so that they would be infertile until a conscious step was taken to achieve fertility. To accomplish prompt restoration of fertility, a method would be needed that actively reversed the immunological infertility—before vaccination wore off with time. A search for such a method with a focus on the development of antibodies to the female hormone chorionic gonadotropin has been under way for well over a decade (47). Even if the medium-term technical problems are resolved, it will take many years of carefully controlled studies with large numbers of women volunteers to determine how long it takes for the effect of the antifertility vaccine to wear off, whether all women are then able to produce normal babies, and whether there are serious side effects after extensive use of such vaccines.

Current Barriers to Contraceptive R&D

If only these six projects, and no others, were completed successfully, the choice for human fertility control would be vastly expanded for all constituencies—poor and affluent, prochoice and anti-abortion, female and male. What are the chances that this can be accomplished? The following analysis is presented primarily from a U.S. perspective, but it has global ramifications. The complexities of developing any modern drug—contraceptive or therapeutic—restrict such endeavors for all practical purposes to the United States, Japan, a handful of Western industrialized countries, and perhaps eventually China and India. But at present the United States still has an overpowering influence, partly because it represents such an important market.

Two of the six agenda items—a new antiviral spermicide and a reliable ovulation predictor—require only the conventional incentives of the marketplace. There is no dearth of market incentives for antiviral drugs, and research in this field is burgeoning. If use-efficacy against the AIDS virus can be demonstrated, the FDA is likely to expedite marketing of such an agent. An ovulation-prediction test faces only straightforward FDA barriers, typical of any new diagnostic method, and no toxicity expenses (since only a

few drops of urine, saliva, or blood are required).

The other four approaches, however, have certain handicaps, the elimination of which will require major legislative or social changes. (i) They will be used by healthy people—a circumstance for which society tolerates very little risk. (ii) Development times covering one or two decades make any investment extremely risky, be it a company's money or an investigator's career. If initiative and support were to depend on nonprofit or governmental agencies, long-term commitments would have to be made. (iii) Until now, only large, multinational pharmaceutical companies have had the resources and expertise for drug developments of the magnitude of these four contraceptive approaches. Given the long development time, recovery of the investment and generation of profit require a long proprietary position, which the present patent laws do not offer (48). (iv) The legal exposure to liability suits could be extremely risky. Impotence or prostatic cancer—two conditions commonly associated with aging in males—are likely to attract litigation by men who may take their pill for 40 years and then blame it for their misfortune. Cases of permanent sterility would likely be attributed to an antifertility vaccine if millions of nulliparous women opt for such a method of birth control. (v) Large pharmaceutical companies, selling many products and having many stockholders, are likely to be more sensitive to threatened boycotts and political pressures than smaller companies. A menses-inducer may well fall victim to a fear of such pressures, even though it may be the most efficient way to reduce abortions.

How can the hurdles be cleared that now stand in the way of a contraceptive revolution or even of modest progress? History demonstrates that no major advances will occur without the participation of the pharmaceutical industry—in production, distribution, development, and even research. The idea that such decisions should be left to the marketplace is useless, for the market has already spoken: given the cost, time, and litigation risks, it is not worthwhile to invest in the development of new contraceptives. A survey of leading R&D therapeutic categories for 1988 (49) does not list contraceptives even among the first 35 rankings. If society wants a well-stocked contraceptive supermarket, society will have to provide the impetus. Of all incentives, addressing the litigation problem in the United States would be of overriding importance. In fact, this is precisely the area where some moves have finally been initiated by legislators prompted by the crisis in vaccine production and the even bigger need for R&D of new vaccines for infectious diseases, from AIDS to malaria (50). Strangely, the similarity in the problems faced by the developers and producers of vaccines and most contraceptives has not yet been recognized in legislative circles.

Modification of Product Liability

The National Childhood Vaccine Injury Act of 1986 was introduced by Congressman Henry A. Waxman and constitutes a form of no-fault insurance against possible injuries from the seven pediatric vaccines (51). The rationale for this limitation was that all children must receive such vaccinations to attend school and that a few are bound to be harmed by such compulsory vaccination. Manufacturers of these vaccines threatened to withdraw from the field because of ever-increasing liability suits, and the Waxman bill was designed to stem such a crisis in vaccine production. Revenues come from a special tax imposed on any childhood vaccine. Like any insurance system, the beneficiaries are expected to pay the premium for risk protection.

The Waxman bill does not address itself to the problems of other vaccines, whose administration is not obligatory, nor does it pay attention to the even more serious problem associated with the

development of new vaccines. It took another national calamity, the AIDS epidemic, and the public's interest in an AIDS vaccine, for the California legislature to examine remedies to the product liability barrier standing in the way of vaccine research. The bill introduced by Assemblyman John Vasconcellos (52) is specifically limited to AIDS and applies only to California. However, it represents a promising model for federal legislation covering other vaccines and, as I wish to emphasize, also for contraceptives.

The key provisions of the California bill are that such a vaccine is recognized as "unavoidably unsafe" and thus exempt from strict liability lawsuits. The bill's key feature of restricting the manufacturer's liability and of funding compensation for medical costs, loss of earnings, and pain and suffering out of an extra charge imposed on the price of the vaccine, would be essential in the contraceptive field. Improvements can be made in these legal models (53), notably a further restriction of tort law application, which is opposed by trial lawyers' lobbies, as are most other provisions of these bills.

Contraceptives and vaccines are obvious targets for superlitigation, because they are not curative drugs to be taken by people already ill; they are administered to healthy people to prevent a condition that the person may never get. Even though a no-fault insurance program, structured around self-funding, would be the single most important incentive for the gradual reentry of the pharmaceutical industry into the field of contraceptive innovation, there are differences in perception between vaccines and contraceptives that operate against extending any special incentives to the latter class.

The societal and personal costs of an undesired pregnancy and of an unwanted child are simply not equated by the public to the immediately evident health consequences of a disease, be it measles or AIDS. Among some groups in the United States, contraception is inherently suspect because of its actual or perceived effect on sexual mores. Finally, U.S. society is likely to look askance at incentives that, directly or indirectly, may benefit pharmaceutical companies, when such firms are generally among the most profitable sectors of U.S. industry. But when another decade or two of minor improvements of existing methods, or even of diminished contraceptive choices, has passed, and the number of abortions, legal or illegal, has not dropped significantly, when this bitter pill is tasted by the next generation, then the time may be ripe for substantive changes.

Conclusion

In view of the present political and social climate in the United States, and the minimal participation of the pharmaceutical industry in contraceptive development, all we can expect well into the beginning of the 21st century are minor modifications of existing methods: different delivery systems for steroids, possible improvements in sterilization techniques and barrier methods, more precise indications of the safe interval, and possibly a more realistic reconsideration of the IUD option. Such modest developments will extend contraceptive use patterns, but they will not affect our total dependence on conventional 19th- and 20th-century approaches to birth control.

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