SOME EFFECTS OF THE CLINTON HEALTH CARE REFORM PROPOSALS ON REGULATED ASPECTS OF THE PHARMACEUTICAL INDUSTRY†

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Plainly, the most significant and the most direct effects of the Clinton health care reform proposals[1] on the pharmaceutical industry would be on prices, and therefore on profits, cash flow, budgets, and the level and mix of research.[2] Because I am a regulatory lawyer rather than an economist, I will discuss some of the proposals' other probable consequences, which would come to light in areas regulated by the Food and Drug Administration (FDA).

In general, the proposals would broaden and accelerate trends that have been observable for some time as a result of changes already underway in public policy and the delivery of health care. I will refer specifically to medical drugs, but much of what I will say also applies to medical devices.

I. Rx TO OTC SWITCHES

Today, active ingredients that appear in both prescription and over-the-counter (OTC) products generally sell for about the same amount, milligram for milligram, OTC as they do in prescription drugs. The Clinton proposals would increase the number of

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† This Article was delivered at the Symposium on The U.S. Pharmaceutical Industry in the 1990s: Facing Health Care Reform, Regulation, and Judicial Controls, on November 16, 1993, at the Seton Hall University School of Law.

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[1] Working Group Draft (Sept. 7, 1993) [hereinafter Working Group Draft]. The Clinton proposals are embodied in the Administration's proposed Health Security Act, printed in 13 C.B. 1 (1993-3) [hereinafter HSA]. The legislation has been introduced as H.R. 3600, 103d Cong., 1st Sess. (1993), and S. 1757, 103d Cong., 1st Sess. (1993).

[2] *See, e.g.*, F-D-C Reports ("The Pink Sheet"), Nov. 8, 1993, at 6; Elyse Tanouye, *Drug Industry Darkens View of Clinton Health Plan*, WALL ST. J., Oct. 29, 1993, at B4; Thomas D. Kiley, *Government Controls on Drug Prices Ultimately May Stand in the Way of Innovative Medical Research*, NAT'L L.J., Oct. 11, 1993, at S14; F-D-C Reports ("The Pink Sheet"), Sept. 20, 1993, at 17; F-D-C Reports ("The Pink Sheet"), Sept. 13, 1993, at 3; F-D-C Reports ("The Pink Sheet"), Sept. 6, 1993, at 5.

switches of pharmaceutical products from prescription to OTC status.

The proposed drug benefits for Medicare recipients and for the rest of the population covered by the standard benefits package are limited to prescription drugs,[3] and all of the proposed measures to drive down and hold down drug prices[4] are limited to the drugs within the scope of the drug benefits, *i.e.*, prescription drugs. The reform proposals do not cover OTC drugs, and consequently make no attempt to influence their prices. As such, the proposals increase, at least in some circumstances, the existing incentives for manufacturers to switch ingredients from prescription to OTC status, where law and public policy make that possible.

Since the introduction of the general prescription-OTC distinction by regulation in 1938,[5] most OTC drugs have been minor remedies for minor ailments: drugs intended to provide merely symptomatic relief from self-limiting conditions while nature takes its curative course. Over the last decade or so, however, changes in pharmaceutical marketing and FDA policy have transformed the OTC drug market. In July 1993, *The Wall Street Journal* reported that, of the ten top-selling OTC products introduced since 1975, nine had been switched from prescription status.[6] Indeed, the switching of ingredients from prescription to OTC status has become virtually the only practical way to introduce new ingredients to the OTC market.

Among the drugs switched have been significant drugs for significant illnesses, including antihistamines, analgesics, sleep aids,

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[3] Working Group Draft, *supra* note 1, at 6, 20, 25, 36, 38, 194; HSA, *supra* note 1, §§ 2001(a) (amending 42 U.S.C. § 1395x(t)(2)) (definition of "covered outpatient drug" for purposes of Medicare coverage), 1122 (outpatient prescription drugs and biologicals covered in comprehensive benefits package).

[4] Working Group Draft, *supra* note 1, at 43 (Breakthrough Drug Committee), 76-77 (health plans to use single-source suppliers), 195-98 (cost containment: rebates, incentives for use of generic drugs, reimbursement policies, equal access to discounts); HSA, *supra* note 1, §§ 1503(i) (Breakthrough Drugs Committee), 1572 (Advisory Council on Breakthrough Drugs), 1407(a)(6) (preemption of state laws that would restrict health plans from "requiring the use of single-source suppliers for pharmacy, medical equipment, and other health products and services"), 2002 (payment rules for covered outpatient drugs), 2003 (rebates, equal access to discounts).

[5] *See generally* PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 46-51 (1980). In 1914, the Harrison Narcotics Act required a prescription for opium and coca leaf derivatives. Pub. L. No. 63-223, § 2(b), 38 Stat. 785, 785-86 (1914). The prescription-OTC distinction was given an express statutory basis in the Durham-Humphrey Amendments of 1951, Pub. L. No. 82-215, 65 Stat. 648-49 (1951) (codified principally at 21 U.S.C. § 503(b) (1988)).

[6] Elyse Tanouye & Thomas M. Burton, *More Firms 'Switch' Prescription Drugs To Give Them Over-the-Counter Status*, WALL ST. J., July 29, 1993, at B1.

antifungals, and antimicrobials. Switches are contemplated for H_2 antagonists,[7] non-steroidal anti-inflammatory drugs,[8] and antivirals. There has been serious discussion of the potential for switches of anti-hypertensives, muscle relaxants, drugs for urinary tract infections, oral contraceptives, antianginal drugs, and others.[9] Collectively, these are among the largest selling drugs in the country.

The switching of drugs from prescription to OTC status is a complex matter. Regulatory approval by the FDA is needed.[10] Generally, dosage strength, packaging, labeling, distribution channels, and marketing techniques all change. Because not all prescription drug manufacturers are well-positioned to market OTC products, licensing agreements, joint ventures, and other business arrangements may be needed to make a switch successful. As a result, the structure of the pharmaceutical industry changes. Regulatory oversight of advertising moves from the FDA (which regulates advertising of prescription drugs) to the Federal Trade Commission (which regulates advertising of OTC drugs).[11]

Historically, the criteria for OTC status were (1) relatively low toxicity and other potential for harmful effect (*e.g.*, low potential for abuse, misuse and addiction, absence of significant interactions with other drugs or foods, and absence of masking of symptoms of serious disease); (2) relative ease of effective use; and (3) possibility of writing adequate directions for safe and effective use by the general public.[12] The breakthrough in public policy came when it was recognized that OTC access can be appropriate even when an initial differential diagnosis by a physician is necessary.[13] In the

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7 *E.g.*, F-D-C Reports, Sept. 13, 1993, at 11 (cimetidine).

8 *E.g., id.* at 9 (naproxen).

9 *See generally, e.g.*, NDMA, Proceedings of Conference on Rx-to-OTC Switch: The Next Generation: Empowering the Consumer (Wash. D.C. Sept. 15, 1992); Marian Segal, *Rx to OTC: The Switch Is On*, FDA Consumer, Mar. 1991, at 9; NDMA, Rx-OTC: New Resources in Self-Medication . . . A Symposium (Wash. D.C. Nov. 1, 1982).

10 *See generally, e.g.*, Daniel R. Johnson, *Policy Developments Affecting Over-the-Counter Drugs*, 41 FOOD DRUG COSM. L.J. 257, 263-66 (1986); Gerald M. Rachanow, *The Switch of Drugs from Prescription to Over-the-Counter Status*, 39 FOOD DRUG COSM. L.J. 201 (1984); Peter B. Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status*, 37 FOOD DRUG COSM. L.J. 427 (1982).

11 Memorandum of Understanding Between the FTC and the FDA, pt. III (Sept. 9, 1971); FDA, *Compliance Policy Guides* 7155m.01 (Food and Drug Administration), Oct. 1, 1980.

12 *See* 21 U.S.C. § 353(b)(1) (1988); 21 C.F.R. § 330.10(a)(5) (1993); United States v. El-O-Pathic Pharmacy, 192 F.2d 62 (9th Cir. 1951); United States v. An Article of Drug Labeled Decholin, 264 F. Supp. 473 (E.D. Mich. 1967).

13 The breakthrough is illustrated in the FDA's decisions to permit OTC marketing of: (1) bronchodilators for treatment of asthma, 41 Fed. Reg. 38,312, 38,370-74 (1976); 47 Fed. Reg. 47,520, 47,522 (1982); 51 Fed. Reg. 35,326, 35,332 (1986); and

case of certain diseases, once the physician has diagnosed the condition and reported the diagnosis to the patient, the patient can take responsibility for obtaining the necessary drug—to treat either an ongoing chronic condition or a temporary but recurrent condition. That this breakthrough did not occur until the 1980s is, with hindsight, somewhat surprising because insulin (a drug for a serious condition not diagnosable by consumers) has been available OTC for decades.[14]

OTC status (together with the availability of drugs in neighborhood pharmacies and food stores) has some clear advantages for consumers and third-party payers. It avoids the costs of some subsequent visits to the doctor—for consumers, it saves the cost of travel and lost time from work, a portion of the cost of seeing the doctor, and the cost of preparing and sending a claim to the insurance company; for third-party payers, it saves the rest of the cost of the visit to the doctor, and the administrative cost of processing the patient's insurance claim. OTC status also has potential medical benefits because it makes access to drugs easier and faster.

Under current practice and the Clinton proposals, however, there is one clear disadvantage for consumers, which in some cases may reduce or eliminate the incentive to switch from prescription status: OTC drugs are not covered by insurance. If more and more medically and economically important chronic- or recurrent-use drugs are switched to OTC status, will consumers be as faithful in buying them when they have to pay 100% of the cost? Will there be significantly reduced patient compliance with physicians' instructions, with resultant adverse medical effects? With respect to individual ingredients, a manufacturer will have to compare, *inter alia*, the benefit of escaping the price-constraining mechanisms created by health care reform with the loss of sales that may result from consumer resistance to paying the full price.

It seems possible that the economic effects of Rx-to-OTC switches will eventually lead to political pressure to extend insurance coverage to at least some OTC drugs. If, and to the extent that, insurance coverage is extended, then presumably the Clinton proposals would apply, and the new additional incentives for Rx-to-

(2) antifungals for treating recurrent vaginal yeast infections, 47 Fed. Reg. 12,480, 12,480, 12,501-06, 12,511-12 (1982); 54 Fed. Reg. 51,136, 51,156 (¶ 35), 51,157 (¶¶ 9, 12, 13) (1989); in 1990, the FDA, after previously declining to permit OTC marketing of these products, approved Schering's Gyne-Lotrimin (clotrimazole) for OTC use; in 1991, it approved Johnson & Johnson's Monistat-7 (miconazole) and Bayer's Mycelex (clotrimazole) for OTC use.

[14] TEMIN, *supra* note 5, at 55-56.

proposals would apply, and the new additional incentives for Rx-to-OTC switches would disappear or diminish in scope. Other marketplace forces, however, may continue to lead to some switches.

II. Redirection of Sales Forces for Prescription Drugs

In the past, the principal focus of prescription drug marketing has been individual physicians. Long after physicians had generally stopped making house calls, many pharmaceutical firms maintained large sales forces of detailmen (later, detailpersons) to make personal calls on physicians to discuss individual drug products. The foundation for such a sales strategy was the fact that the locus of drug product selection was the individual physician.

In recent years, the locus of product selection has been shifting away from individual physicians, and the Clinton proposals would magnify this shift. The proposals would bring about a very significant centralization of decision-making authority over medical practice, including product selection. The proposals would greatly strengthen the economic forces driving physicians into health maintenance organizations, preferred provider organizations, and other practice groups or plans that have common management and prepayment or common standards for care. In such plans, it is the management, acting through formulary committees and similar bodies, rather than individual physicians, that will have the principal influence on which drug products are prescribed.

The pharmaceutical firms would, therefore, have to continue to redirect their sales efforts toward centralized rather than decentralized decision-makers. The casual drop-in visits to individual physicians, the leaving of pens and prescription pads with company logos, and the direct continuing medical education provided by detailpersons would diminish, and would be replaced by more formal presentations to committees and opinion leaders within centralized health plans.[15] Even as to those audiences, however, individual face-to-face visits might be reduced in favor of newly developing modes of promotional communication (*e.g.*, cable television networks and interactive televised communications).

Some detailing of individual physicians might continue.[16] It

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[15] The Chairman and Chief Executive Officer of Glaxo, Inc. has suggested that the Clinton proposals would lead to a significant reduction in pharmaceutical industry support for continuing medical education generally. *See* F-D-C Reports ("The Pink Sheet"), Oct. 11, 1993, at 6.

[16] It was recently reported that Whittle Communications L.P. is facing difficulty in recruiting pharmaceutical firms to sponsor the second phase of its Medical News Network, which delivers news and information to physicians' offices via satellite. Patrick

still might be cost-effective for pharmaceutical firms to pay visits to medical opinion leaders. Where formularies include competing products in the same therapeutic category, product promotion to individual physicians might still be worthwhile. Detailpersons might also visit individual physicians to seek to have them influence decisions of formulary committees. In a world in which product selection is severely constrained by the central managements of health plans, however, the relative importance of detailing and, indeed, of pharmaceutical advertising to individual physicians (in medical journals, conventions of professional societies, etc.) might diminish; and the relative importance of presentations to formulary committees might greatly increase.[17]

The FDA regulates the promotion of prescription drugs;[18] and, as methods of promotion change, the focus of the agency's regulatory efforts will have to change accordingly. If presentations to formulary committees become *the* crucial means to promote drugs, it is difficult to believe that the FDA will not seek to regulate such presentations closely. It is not yet clear what techniques the agency will find most effective in ensuring that products are not misbranded during such presentations. The agency's authority to regulate oral presentations, as distinct from written and other graphic presentations, is relatively limited.[19] It is possible the agency will seek, and receive, new statutory authority to regulate presentations relating to inclusion in formularies.

III. NEW CONTENT OF DRUG PROMOTION—COMPARATIVE AND COST-EFFECTIVENESS CLAIMS

Increased use of formularies by centrally managed health care plans would tend not only to drive down pharmaceutical prices, but also to foster more intense competition among drugs within the same therapeutic category on the basis of comparative safety

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ST. J., Nov. 15, 1993, at B8. Thus, it apparently remains to be seen whether new technologies will replace pharmaceutical sales forces for direct communications to individual physicians.

17 It is conceivable that the Clinton proposals would lead to increased prescription drug advertising to the general public, to induce consumer demand for their health care plans to include particular products. Inclusion of heavily promoted products might become an element in the competition among plans for consumers.

18 *See, e.g.*, Richard M. Cooper, *The Food and Drug Administration's Authority to Regulate Miscellaneous Statements by Pharmaceutical Manufacturers*, 7 J. PHARM. MKTG. MGT. 99 (1992).

19 *See generally* Lars Noah, *Death of A Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives?*, 47 FOOD & DRUG L.J. 309 (1992).

the same therapeutic category on the basis of comparative safety and effectiveness and comparative cost-effectiveness. The centralization and consequent greater public visibility of product selection is likely to increase decision-making on the basis of comparative data with respect to the major parameters: cost, effectiveness, safety, convenience, quality of life generally, and other elements of overall patient satisfaction.

Managers of health plans would want to know how competing drugs compare in these respects. Federal and state agencies and alliances would also call for such knowledge, and perhaps supply some of it.[20] The economic significance of decisions by such parties would justify attempts by pharmaceutical firms and others to generate the relevant data.

The FDA would closely regulate the provision of such information by regulated firms. The agency already has undertaken to improve its ability to regulate cost-effectiveness claims. In at least two instances, it has challenged such claims by pharmaceutical firms, and it is planning to issue a policy governing cost-effectiveness claims.[21]

Any drug approved by the FDA has satisfied demanding requirements for proof of effectiveness and safety, as demonstrated in clinical trials and other experimental settings.[22] In the past, such approval has generally been sufficient to win new drugs some usage by individual physicians with their patients. In the world of centrally managed health plans with established formularies, however, mere FDA approval might be insufficient to gain substantial market usage. Obviously, price would be a significant factor in gaining inclusion in formularies. Some apparent advantage in safety, effectiveness, patient compliance, and convenience (as demonstrated in clinical trials) might also prove important in gaining a foothold in the marketplace. Even where important competing drugs have large price differences, comparative studies could attract very substantial interest—as the comparative studies of streptokinase and tissue plasminogen activators (TPA) illustrate.[23]

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[20] Laura D'Andrea Tyson, Chair of the President's Council of Economic Advisors, recently called for increased spending for research on comparative cost-effectiveness of competing therapies. She noted that a reformed health care system would create incentives to develop and use such information more widely. M-D-D-I Reports ("The Gray Sheet"), Oct. 25, 1993, at I&W-7.

[21] F-D-C Reports ("The Pink Sheet"), Sept. 13, 1993, at 15; F-D-C Reports ("The Pink Sheet"), Nov. 1, 1993, at 8; Washington Drug Letter, Nov. 29, 1993, at 2.

[22] *See* 21 U.S.C. § 355 (1988); 21 C.F.R. pt. 314 (1993).

[23] *See, e.g.*, Richard L. Hudson, *Genentech's Heart Drug TPA Appears Only to Equal Its Rivals, Report Says*, WALL. ST. J., Sept. 2, 1988, at 34; Marilyn Chase, *Old Heart Drug*

Already, pharmaceutical firms are experiencing demand from customers for data on outcomes and cost-effectiveness. To meet that demand, some firms are including outcomes and cost-effectiveness measures in pre-approval clinical trials, even though such data generally are not required for approval by the FDA.[24] In the future, such studies are likely to extend beyond drug-drug comparisons to comparisons between drugs and other modes of treatment (*e.g.*, surgery).

The proposed National Quality Management Program (to be administered by an advisory council to the National Health Board),[25] alliances, and health plans are all likely to increase the effective demand for such data, including data on outcomes and cost-effectiveness in actual clinical use.[26] The plans themselves would provide the patients for such studies. The actual studies might be conducted by or for alliances, plans, pharmaceutical firms, and the government. The results of studies of outcomes would make possible more detailed examinations of absolute and comparative safety, effectiveness, and cost-effectiveness in actual widespread use than heretofore have been customary.

The stakes in such studies would be very large. The health of patients, general standards and methods of care, large health-care expenditures, the reputations of providers, and market shares for individual medical products might be determined by the results of such studies and how they are interpreted. Even a study carried out, for example, on data from one health care plan might, once publicly presented, affect decisions across the country.

Such studies raise significant questions for public policy and law. Causation is difficult to establish, and statistical studies of outcomes are rarely definitive. Physicians, epidemiologists, statisticians, and others with relevant expertise can differ about inclusion and exclusion of data, the handling of incomplete data, the failure to control for possibly relevant variables, and the analyses that led to the particular conclusions reached. Because such studies would usually be based on data keyed to patient names or other identify-

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Works as Well as Costly TPA in Study, WALL ST. J., Mar. 9, 1990, at B1; Susan Okie, *Lowest-Cost Heart Drug Safer, Researchers Say*, WASH. POST, Mar. 3, 1991, at A4, col. 1.

For an example of a comparative study of antihypertensive drugs, see Michael Waldholz, *Study Favors Older Remedy As Heart Drug*, WALL ST. J., Jan. 19, 1990, at B1.

24 F-D-C Reports ("The Pink Sheet"), Nov. 1, 1993, at 9.

25 Working Group Draft, *supra* note 1, at 100; HSA, *supra* note 1, §§ 5001-13.

26 The role of the National Quality Management Program in developing and disseminating such data is discussed at Working Group Draft, *supra* note 1, at 105-06. *See also* HSA, *supra* note 1, §§ 5001-13.

ing information, and because generally the data would be owned by plans, alliances, or government agencies, access to the data on the part of other interested parties—organized patient groups, providers, and manufacturers—might not readily be granted. Financial relationships between investigators or their institutions and interested parties (*e.g.*, manufacturers, providers, plans) might raise questions about bias in studies. Should the law, in the interest of fairness, guarantee to interested parties some form of access, with patient privacy protected? Should the law require some form of public notice when such studies are undertaken, at least with government data or government funding? Should some disclosure of conflicts of interest be required, by law or practice?[27]

An anticipated stream of studies of associations between particular therapies and particular types of outcomes might be analogous to the "carcinogen-of-the-month" syndrome that was experienced in the 1970s: results of new carcinogenicity bioassays of marketed products would be announced immediately in the general press and create public concern, and scientific peer review would follow only later, and sometimes raise questions about the validity or interpretation of the results previously reported. In the meantime, however, consumer confidence in products would have been shaken, and manufacturers would have been scrambling to find substitute ingredients for their products.

If a study of outcomes unexpectedly concludes that a therapeutic approach in current use is associated with excess mortality or morbidity, or that one current therapy is associated with better outcomes than another, how would the pressure for immediate action be reconciled with the desirability for peer review and confirming data? Should decisions in the wake of such studies be left wholly to the judgment and discretion of individual health plans? Given that legally permissible alliances and health plans would be limited in number and would therefore have significant market power created by law, should the law or public policy require that any particular standard of proof be met and/or that any particular procedures be used before those with the centralized power to change practice patterns exercise that power? Should such mandated standards and/or procedures, if any, be limited to governmental agencies? If standards and procedures are not mandated by law, how, in a world of much more centralized and visible deci-

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[27] *See, e.g.*, Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573 (1993); Jerome P. Kassirer & Marcia Angell, *Financial Conflicts of Interest in Biomedical Research*, 329 NEW ENG. J. MED. 570 (1993).

sion-making, should decisions be made about the translation of studies of outcomes into actual medical practices?

One can expect that these issues will be debated in many forums in addition to formulary committees, including professional societies, medical journals, government agencies, congressional committees, the general press, and the courts. New legislation on this set of issues may be warranted.

For the FDA, increased attention to economic aspects of product performance would create a new field for regulatory policymaking and related compliance and enforcement activities. The agency would have to develop new expertise in evaluating economic claims with respect to drugs. In this as in many other respects, health care reform would provide increased employment for economists—in both the public and the private sectors.

The FDA already has rigorous requirements for comparative claims by manufacturers and distributors relating to safety and effectiveness,[28] although the agency does not regulate assessments of products by parties acting independently of regulated firms. Because *comparative* cost-effectiveness claims involve comparative claims of safety or effectiveness, presumably the same standards would apply to claims made by manufacturers or distributors. The agency would also have to develop new regulatory standards for comparative economic claims with respect to regulated products.[29]

IV. THE GENERIC DRUG APPROVAL PROCESS AS AN ADVERSARIAL PROCESS

The Clinton proposals would strengthen the economic pressure to substitute generic for brand-name drugs whenever such substitutions are possible. As a result of economic pressures for use of generic drugs, which would only be strengthened by the Clinton proposals, brand-name companies (through acquisitions or otherwise) are becoming suppliers of generic copies of their own and competitors' drugs; and the generic industry, having survived the scandal of the late 1980s, will expand its offerings of competitive products.

The increased threat that a first generic product would pose to

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28 *See, e.g.*, 21 C.F.R. § 202.1(e)(6)(ii) (1993) (advertising).

29 The FDA Division of Drug Marketing, Advertising and Communications is already receiving more questions from members of the Pharmaceutical Manufacturers Association with respect to cost-effectiveness claims than with respect to any other subject. PMA NEWSLETTER (Pharmaceutical Manufacturers Association), Nov. 22, 1993, at 5.

the pioneer drug it copies would thus intensify the incentives, and so, too, the efforts, of research-based firms to oppose FDA approval of generic drugs.

One characteristic of the FDA's generic drug approval process that would intensify under the Clinton proposals is its adversarial character. The process for approving new drug applications for non-generic drugs is almost always conducted privately between the applicant and the FDA, with no involvement by any competitor or other third party. The process for approving abbreviated applications or the so-called "paper" applications for generic drugs has become, in some instances, adversarial, as brand-name firms file objections to approvals of new generic products on scientific or other grounds.[30] Although third parties cannot formally intervene in the application-approval proceeding, they can initiate parallel proceedings in order to have their views considered.

The FDA is not well-positioned to conduct drug-approval proceedings in an adversarial context. As challenges to generic approvals become more frequent under the Clinton proposals, the agency would have to develop new procedures to accommodate the economic and legal environment in which approvals of generic drugs are sought and challenged.[31]

CONCLUSION

In sum, the Clinton proposals would strengthen, broaden, and accelerate changes of regulatory significance in the way pharmaceutical firms do business that are already under way, and that probably would continue no matter whether or what health care reforms are adopted.

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[30] *See, e.g.*, Schering Corp. v. Shalala, 995 F.2d 1103 (D.C. Cir. 1993).

[31] The Federal Trade Commission is investigating whether firms with approved pioneer products have used the regulatory system improperly to impede generic competition. F-D-C Reports ("The Pink Sheet"), Nov. 22, 1993, at 3.