Massachusetts Institute of Technology
Sloan School of Management

Room E52-452
50 Memorial Drive
Cambridge, MA 02142-1347

Telephone: 617 253-2665
Facsimile: 617 258-6855
E-Mail: cbcrndt@mit.edu

Ernst R. Berndt
Louis B. Seley Professor of
Applied Economics

June 13, 2003

Comments by Ernst R. Berndt to the Food and Drug Administration
Topic: Mandatory Switches of Prescription Drugs to Over the Counter

Submitted to FDA Docket number 98P-0610/cp1
Convert Allegra/Allegra-D, Claritin/Claritin-D, Zyrtec to OTC

Mark McClellan, M.D., Ph.D., Commissioner
US Food and Drug Administration
5600 Fischer s Lane
Rockville, MD 20857

Dear Mark:

Pfizer Inc. has asked me to help evaluate the likely impacts of mandatory Rx-to-OTC switches, based in part on my previous work on such switches (e.g., Berndt , Kyle and Ling, , "The Long Shadow of Patent Expiration: Generic Entry and Rx to OTC Switches, NBER/CRIW, 2003). The views I express in this letter are my own, and do not necessarily reflect those of MIT, NBER, or of research sponsors at MIT and the NBER. Although FDA's primary responsibility to the public is to evaluate the safety and efficacy of pharmaceuticals and other medical technologies, in some cases, economic considerations can be important in helping to guide FDA policy toward pharmaceuticals. Following are some economic considerations I think are very important to contemplate with respect to policy surrounding the issue of mandatory Rx-to-OTC switches.

I understand that the FDA is considering potential policy changes in this area, and I thought it might be helpful if I shared with you some of my thoughts on the subject. I believe it is important for the FDA to consider whether there is a clear public health benefit to mandatory switches, so I will direct my remarks to that issue. My comments are not specific to any single therapeutic class of drugs, but focus instead on the more important question of setting a precedent in this area. In brief, among the three classes of parties affected by any mandatory switch, in my opinion, the manufacturers clearly lose, the

98P-0610 C50

insurers clearly gain, and it is not possible to determine *a priori* whether consumers are better or worse off. The latter point suggests that it is not prudent to "force" an Rx to OTC switch based on public health interests.

It is critical to distinguish between voluntary and mandatory switches. The work I did was on the voluntary actions of four companies to take their H2-antagonists OTC. Market pressures on these prescription drugs that were either off-patent or shortly to go off-patent led the patent holders to find the new indications that would permit them to be considered for OTC status. We can presume that from the companies' vantage, this was an efficient solution, although the overall impacts on consumers were uncertain.

Mandatory switches leave the innovating pharmaceutical companies unambiguously worse off, because they lose the freedom to optimize the switch date. Additionally, a mandatory switch *transfers* producer surplus from the manufacturer to covering insurance companies as the insurers no longer pay for the product. To the extent that the switch results in a lower average price for the product, the manufacturer is likely to receive lower revenues. While a reduced OTC price offers potentially offsetting revenues from attracting new customers to a product, that opportunity already exists in the absence of a mandatory switch so it cannot, on net, be beneficial to the manufacturer.

The impact of a mandatory switch on consumers is uncertain, depending in part on the consumers' drug insurance status. First, in the short-term there is a *transfer* to insurers in the form of the revenues that the insurer no longer has to pay for the drug and instead the previously insured consumer does. Since the insurer already has collected premiums covering this cost that it no longer pays out, it is a windfall gain to the insurer and a loss to consumers (at least in the short run, until premiums are recalculated and put in place). Over time, it is reasonable to expect that competitive pressures on insurers will force them to pass along these cost savings to consumers either through more generous benefits or reduced premiums. Thus, the transfer from manufacturers to insurers is actually a transfer from manufacturers to consumers that insurers will capture in the short-term. The tricky issue, however, is how long the short-term will be. That will depend on many factors and is not easily predicted. Worse, if premiums are "sticky," the insured consumer may never wholly benefit.

On the consumer benefit side, insured consumers who do not perceive the advice of a prescribing physician to be more valuable than the cost of the physician's visit are saved the difference between the cost and the perceived benefit. Some gain may also accrue to the insurer who pays for fewer physician visits. There is, of course, a potentially offsetting cost to consumers who undervalue the advice of a physician.

Furthermore, to the extent that the switch results in a lower OTC price, some uninsured patients benefit from the lower price and some consumers who would not have purchased at the higher price receive additional consumer surplus. The size of these gains depends, of course, on the nature of the demand for the product in question and on the magnitude of the price reduction that results from moving the product to OTC status. In view of the fact that mandatory switches are likely to involve products under patent protection, whether they be Rx or OTC, the size of the price reduction is by no means certain.

In the short-term it is highly speculative whether the losses suffered by one class of consumers as a result of the mandatory switch are offset by gains to others. There are clear gains to insurance companies, but these gains are transfers and do not contribute to overall social welfare. Hence, the

impact of the policy on consumers is uncertain and ambiguous, and there is no clear gain in social welfare.

The most important concern with mandatory Rx-to-OTC switches is that this reduces incentives to innovate. It does this in two ways. First, the immediate transfer of resources from manufacturers to insurers leaves fewer resources to invest in R&D. Second, and more important, pharmaceutical manufacturers make product development decisions in anticipation of the profits that will eventually flow from those innovation efforts. To the extent that compulsory OTC switching policies alter the present value of expected returns on product development efforts, companies are likely to reduce their research and development efforts. Marginal R&D products will be terminated, leading to fewer discoveries. Consumers will lose access to beneficial new therapies. In the consumer surplus or welfare context, this equates to a loss in all consumer surplus for all products that are not brought to market due to the reduced R&D activities. This is a permanent loss in consumer welfare. The Hughes, Moore and Snyder NBER working paper (#9229, October 2002) on "Napsterizing Pharmaceuticals" provides a reasonably good estimate of this loss. They find that for every dollar saved by reducing returns to today's products, the present value of lost future products that are never invented because the market is less attractive is roughly three dollars.

In my view, the consumer is not unequivocally better off under a mandatory switch of a prescription drug to OTC status. I am not convinced that it is in the government's interest to reduce the return to pharmaceutical innovation, and it seems even less clear to me that the FDA has an interest in an action that has negative consequences for consumer health in the future, and an ambiguous effect on consumer welfare in the short term.

I would welcome any opportunity to present my findings and assessment of these issues with you and your staff at your convenience.

Sincerely,

Ernst R. Berndt

cc: US Food and Drug Administration
Dockets Management Branch
5630 Fischers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852
Fax: 301-827-6870

Tomas Philipson, Ph.D.
Office of the Chief Economist

Food and Drug Administration
5600 Fischers Lane
Rockville, MD 20857

Randall S. Kroszner, Ph.D.
Council of Economic Advisors
Eisenhower Executive Office Building
17th Street and Pennsylvania Avenue NW
Washington, DC 20502

Harvey Rosen, Ph.D.
Council of Economic Advisors
Eisenhower Executive Office Building
17th Street and Pennsylvania Avenue NW
Washington, DC 20502