OBJECTIVE: To compare this switch with prior Rx-to-OTC switches and discuss its economic, clinical, and public health implications.

METHODS: The FDA held meetings in May 2001 to determine if prescription (Rx) second-generation antihistamines (SGAs) should be sold over-the-counter (OTC). This meeting warranted much attention because a party other than drug manufacturers requested the switch, and SGAs’ patents have not expired. Literature reviews of prior switches and allergic rhinitis (epidemiology and clinical management) were conducted. Microeconomic theories were used to examine economic implications of switching SGAs.

RESULTS: Past experiences of switching drugs to OTC status (i.e., topical hydrocortisone, H2-blockers) have resulted in lower prices and greater consumer surplus and availability. It is unclear if similar conclusions can be drawn about SGAs, whose patent protection differentiates them from prior switches of patent-expired drugs. Predictions of the switch’s economic consequences (i.e., pricing and social welfare) cannot be made without full knowledge of demand elasticity in the antihistamine (first- and second-generation) market. Additionally, a mandated switch prior to patent expiration may discourage research and development. From a clinical perspective, selling SGAs OTC may reduce physician intervention, leading to drug misuse and missed diagnoses of severe co-morbidities (e.g., asthma). From a public health perspective, if SGAs are removed from Rx formularies post-switch, patients could be responsible for total drug acquisition costs. This may diminish availability for financially vulnerable populations (i.e., Medicaid recipients).

CONCLUSIONS: Selling SGAs OTC may increase availability and decrease the use of sedating antihistamines. However, the net impact of their switch remains unknown. The lack of generic competition implies prices for SGAs may not fall nor may social welfare improve. Cost-benefit analyses are needed to determine if benefits of the switch will outweigh costs of misdiagnoses and misuse. Lastly, the impact of the switch on vulnerable populations must also be explored.
OBJECTIVE: To estimate the long-term benefits of chemopreventive tamoxifen and mammography screening in women who are healthy but at high risk of developing breast cancer. Long-term benefits were defined in terms of life expectancy (LE) gains achieved through addition of chemopreventive tamoxifen (5-year therapy) to routine mammography screening.

METHOD: A Markov process with time-and-state-dependent transition probabilities was developed. Two hypothetical cohorts of high-risk women were initiated at age forty and were followed over their lifetime. The first cohort consumed tamoxifen and underwent routine mammography screening as per recommendations of the American Cancer Society (ACS). The second cohort (control cohort) did not consume tamoxifen and underwent mammography screening at rates observed in general population settings (these rates are much lower than the ones recommended by the ACS). Tamoxifen intervention was modeled based on the 5-year Breast Cancer Prevention Trial results. Data from published analyses, which investigated effects of mammography screening on breast cancer mortality, was used to model mammography screening intervention. Mortality data were obtained from life tables and other published sources.

RESULTS: Tamoxifen coupled with routine mammography screening prolonged the average survival of cohort members who started consuming the drug at age of forty by 86.14 days as compared to the control group. One-way sensitivity analysis was performed to evaluate the potential impact of each assumption on average cohort survival. Sensitivity analysis involved varying intervention-related effectiveness parameters, rates of intervention-related adverse events, compliance with intervention, and mortality rates associated with different health states in the model. For all variations, tamoxifen plus routine mammography screening group had higher average survival than the control group.

CONCLUSION: The model was found to be robust to sensitivity analysis and hence tamoxifen plus routine mammography screening can be expected to increase survival among women who are at higher risk of breast cancer.

AN INTERIM COST AND OUTCOME COMPARISON ALONGSIDE A PROSPECTIVE RANDOMIZED CLINICAL TRIAL COMPARING EARLY INTENSIFICATION WITH BONE MARROW TRANSPLANTATION (BMT) TO CONVENTIONAL DOSE CHEMOTHERAPY FOR PREVIOUSLYUNTREATED PATIENTS WITH AGGRESSIVE NON-HODGKIN'S LYMPHOMA

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OBJECTIVES: To identify and compare the costs and outcomes associated with early intensification with bone marrow transplantation versus conventional dose chemotherapy for previously untreated patients with aggressive non-Hodgkin's lymphoma at high risk for relapse.

METHODS: Costs and patient responses (outcomes) were evaluated for the first 84 patients in this ongoing prospective randomized clinical trial. Data were compiled from November 1995 until May 2001. Patient outcomes were retrieved from the institutional Protocol Data Management System and costs were retrieved from institutional financial and administrative databases. Direct costs included hospital, clinic, pharmacy, and physician costs. Pearson chi square was used to analyze the association between costs and treatment group.

RESULTS: Forty-four patients received conventional dose chemotherapy and 40 patients received BMT. The average cost of therapy per patient for conventional dose chemotherapy was $61,515 (range $5,360 to $186,684) and the average cost per patient for BMT was $133,365 (range $11,868 to $431,248). Outcomes were categorized as complete response (n = 36), partial response (n = 35), and other (incomplete to date n = 13). Costs were categorized as low (<$45,000), medium ($45,000–$80,999), medium high ($81,000–$125,999), and high (> $126,000). In the conventional dose chemotherapy group 61.1% of patients had a complete response and 38.9% of patients in the BMT group had a complete response. Costs for conventional dose chemotherapy patients were in the low to medium cost groups, and costs for BMT patients were in the medium-high to high cost groups (chi square = 29.42, d.f. = 3, p < 0.001).

CONCLUSIONS: Overall, higher costs were observed in the BMT group, and more complete responses were observed in the conventional dose chemotherapy group.

COLLECTION OF INFECTIOUS DISEASE AND ECONOMIC OUTCOMES FOR NON-HODGKIN’S LYMPHOMA AND MULTIPLE MYELOMA PATIENTS ADMITTED FOR INFECTIOUS COMPLICATIONS UTILIZING A PALM™ HANDHELD

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OBJECTIVES: To evaluate infectious disease outcomes and cost of care for lymphoma and myeloma patients admitted for infectious complications. To evaluate a Palm handheld as a tool for prospective data collection utilizing Pendragon Forms software.

METHODS: Patients admitted to the Lymphoma/Myeloma service receiving anti-infective therapy for infectious diseases were followed. Targeted outcomes were collected prospectively during hospitalization and included length of hospitalization (days), adverse events attributed to the anti-infective, febrile days (>38.3°C),