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A Brief Note on Pharmaceutical Policy

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Perspective

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DESCRIPTION

Pharmaceutical policy is a subset of health policy concerned with the creation, distribution, and use of pharmaceuticals in the context of a health-care system. Drugs (both brand name and generic), biologics (items derived from live sources rather than chemical components), vaccinations, and natural health products all fall under this category. In many countries, a national government agency (the NIH in the United States, the MRC in the United Kingdom, and the DST in India) funds university researchers to investigate the causes of disease, which in some cases leads to discoveries that can be transferred to pharmaceutical and biotechnology companies as a basis for drug development. It can have a considerable impact on the rate of new drug development and the disease areas in which new medications are produced by deciding on its budget, research goals, and which researchers to sponsor. For example, the National Institutes of Health's large investment in HIV research in the 1980s could be seen as a crucial foundation for the various antiviral drugs that have since been developed.

While patent laws are written to apply to all inventions, whether mechanical, pharmaceutical, or electronic, the interpretations of patent law made by government patent granting agencies (such as the United States Patent and Trademark Office) and courts can be very subject-matter specific, having a significant impact on drug development incentives and generic drug availability. For example, in Pfizer v Apotex, 480 F.3d 1348 (Fed.Cir.2007), the United States Court of Appeals for the Federal Circuit invalidated a patent on the "pharmaceutical salt" formulation of a previously patented active ingredient. If the US Supreme Court does not overturn the ruling, generic copies of the disputed medicine, Norvasc (amlodipine besylate), will be accessible considerably sooner. If the Federal Circuit's reasoning in this case is applied more broadly to other patents on pharmaceutical formulations, it will have a

considerable influence on the availability of generic medications (and, conversely, some negative impact on the incentives and funding for the research and development of new drugs).

This is the process of approving a product for sale in a specific jurisdiction. A national agency, such as the US Food and Drug Administration (specifically, the Center for Drug Evaluation and Research, or CDER), the UK Medicines and Healthcare Products Regulatory Agency, or Health Canada, or the Ukrainian Drug Registration Agency, is usually in charge of reviewing and approving a product before it can be sold. Quality, safety, and efficacy are usually the emphasis of the regulatory procedure. A product must demonstrate that it is generally safe (or has a favourable risk/benefit profile relative to the condition it is intended to treat), that it does what the manufacturer claims, and that it is manufactured to high standards in order to be approved for sale. Products are reviewed by internal personnel and expert advisory bodies. Drug costs are regulated in many areas. In the United Kingdom, for example, the Pharmaceutical Price Regulation Scheme aims to ensure that the National Health Service may buy pharmaceuticals at "fair rates." The Patented Medicine Prices Review Board in Canada investigates medicine pricing, compares proposed Canadian prices to those in seven other countries, and evaluates whether or not a price is "excessive." Drug producers must submit a recommended price to the appropriate regulatory agency in certain cases.

Prescriptions may be shaped and informed by pharmaceutical policy. Physicians may be the only ones who may write prescriptions, or specific types of health care providers, such as nurse practitioners and pharmacists, may be allowed to do so. Each type of supplier may be subject to restrictions. This could be in the form of prescribing criteria for a drug, such as limiting its prescribing to a specific type of specialist physician (such as HIV/AIDS drugs to physicians with advanced training in this area), or it could be in the form of special drug lists that a specific type of health care provider (such as a nurse practitioner) can prescribe from. Other providers, such as pharmacists who provide clinical advising services, may also be involved in efforts to encourage the "proper use" of pharmaceuticals. Pharmacists and physicians frequently interact in settings such as hospitals and long-term care facilities to ensure that the best prescribing decisions are made. Pharmacists are reimbursed in some jurisdictions, such as Australia, for doing medication evaluations for patients outside of acute or long-term care settings. Collaboration between pharmacists and family physicians to improve prescribing may also be funded.

Pharmaceutical policy may also include the manner in which pharmaceuticals are distributed to beneficiaries. This involves both the mechanics of drug distribution and dispensing as well as how such services are funded. Some HMOs in the United States, for example, adopt a 'central fill' strategy, in which all prescriptions are packaged and dispatched from a central facility rather than from a neighbourhood pharmacy. Retail pharmacies in other jurisdictions are reimbursed for dispensing medications to qualifying beneficiaries. A state-run approach, such as Sweden's Apoteket, which had a monopoly on retail pharmacy until 2009 and was non-profit, might be used. Smaller, more marginal pharmacies may also be subsidised under the guise of being essential health care providers, according to pharmaceutical policy. This is how the UK's Essential Small Pharmacies Scheme operates.