Product Liability - USA

$4 billion price tag? FDA's proposed generic drug labelling rule

Contributed by **Morrison & Foerster LLP**

March 13 2014

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Introduction

An economic consulting group recently published findings that a Food and Drug Administration (FDA) proposed rule will increase annual healthcare costs by $4 billion. The FDA's proposal, announced in November 2013, will allow generic drug manufacturers to update product labelling with new safety information even if the revised labelling differs from that of the reference listed drug (for further details see "Goodbye to generic pre-emption? FDA publishes proposed rule"). The alarming cost increases announced by this recent study provide further support for those who believe that the FDA simply got it wrong this time.

Background

The FDA's proposed change was a direct response to the Supreme Court's call for action in *PLIVA, Inc v Mensing*(1). In *Mensing*, the Supreme Court held that federal law pre-empted state law 'failure to warn' claims against generic drug manufacturers because the Hatch-Waxman Amendments require generics to use warnings that are identical to the brand name's warnings. Recognising that generic pre-emption could leave some plaintiffs without a failure to warn claim, the Supreme Court nevertheless declared that it:

> *"will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire."*(2)

In response, the FDA issued the rule currently under debate.

The proposed rule allows holders of abbreviated new drug applications (ANDAs) to update product labelling to reflect newly acquired information related to drug safety, regardless of whether the revised label is different from the reference listed drug's label. The proposal permits the ANDA holder to distribute the revised label at the same time that it sends labelling changes in a 'changes being effected' supplement (CBE-0) to the FDA. Simultaneously, the ANDA holder sends labelling changes and supporting information to the reference listed drug manufacturer, which is generally the new drug application holder.

The new drug application holder reviews the information and submits a revised label to the FDA indicating whether it supports the CBE-0 supplement. The FDA evaluates the proposed labels and determines which label should be approved. After that determination, the ANDA holder has 30 days in which to update its labels.

Under the rule, the FDA estimated that net annual costs would range between $44,000 and $385,000, which many critics have suggested is too low. Those critics have also voiced concerns that the proposed rule would serve only to fund the plaintiffs' bar at the expense of public safety.

Potential $4 billion increase

On February 4 2014 Matrix Global Advisors, an economic policy consulting firm, released its findings following a study of the proposed rule. Matrix projected that the changes would add $4 billion annually in US healthcare costs due to increased product liability exposure. The study called the $4 billion figure a "conservative estimate" of the

total cost of the proposed rule, which flies in the face of the FDA's insistence that the rule would "generate little cost".

First, the study contrasted the FDA's stated purpose for the proposed rule – creating "parity" between brand name and generic manufacturers' labelling obligations – with what Matrix believes is the FDA's actual purpose: fixing the "perceived inequality" in a consumer's ability to sue drug manufacturers after the Supreme Court's decisions in *Wyeth v Levine*(3) and *PLIVA, Inc v Mensing*. Next, Matrix criticised several aspects of the FDA's economic impact assessment under the proposed rule. For instance, the FDA did not consider product liability costs, even though the FDA acknowledged that the proposed rule may eliminate generic pre-emption. Instead, the FDA focused only on increased costs associated with extra paperwork and added administrative burdens. The FDA also failed to account for increased insurance premiums or increased CBE-0 filings, and did not even attempt to quantify the benefit from the proposed rule that would come in the form of improving communication to healthcare providers.

The study highlighted that even small price increases for generic drugs could significantly affect drug spending and savings in the United States due to the sheer volume of generic prescriptions. In 2012 generics were responsible for $217 billion of savings – in a year when retail prescription drug spending totalled $263.3 billion. Without generics, retail prescription drug spending would have been $480.3 billion, equivalent to an 82% spending increase. Generic price increases under the new rule would reduce savings attributed to generics, add to total retail prescription drug spending and dramatically change the savings figures.

Finally, the study used brand name product liability costs to project generic product liability costs. Matrix estimated that:

- in 2012, the cost of a brand's product liability exposure equalled "0.4 percent of consumer spending" or $758.3 million;
- dividing this by the 652.5 million brand prescriptions from 2012, brand name product liability spending was approximately $1.16 per prescription; and
- multiplying brand name product liability spending per prescription ($1.16) by the number of generic prescriptions in 2012 (3.4 billion) totalled $4 billion in generic product liability spending.

Although the study used different assumptions to arrive at brand and generic product liability costs, it is clear that these costs represent a significant potential economic impact that the FDA completely ignored. In light of recent healthcare reform and concerns over rising healthcare costs, these numbers are particularly disconcerting.

Some of Matrix's assumptions may be susceptible to criticism. For instance, multiple labels may not create confusion in the marketplace, and the study also assumed that generics' current product liability litigation costs are minimal. However, there is no doubt that the rule will eliminate generic pre-emption, which dramatically increases a generic's product liability exposure. This heightened risk will lead to higher insurance premiums, which in turn may force some generic manufacturers to exit the market or decline to enter the market, causing decreased supply and increased prices.

Criticisms

The Matrix study was the latest in a series of highly critical reactions to the proposed rule. Both lawmakers and industry have criticised the proposal. Congressional Republicans have urged the FDA to "reconsider [its] departure from decades of settled practice" surrounding generic labelling, and the pharmaceutical industry suggests that the rule could result in fewer generic options for the public.

The Republican Party, through Senator Lamar Alexander (the senior Republican on the Senate Health Committee), expressed its displeasure in a letter to FDA Commissioner Margaret Hamburg. The letter noted "grave concerns regarding a regulation… that would directly conflict with [Hatch-Waxman's] longstanding policy". In particular, Republicans identified three main problems with the proposed rule:

- It directly conflicts with the statute.
- It "thwarts" the law's purpose, creating confusion.
- It imposes "significant costs on the drug industry and healthcare consumers".

The Republicans suggested that allowing generic drug manufacturers to revise unilaterally their labelling contradicts Hatch-Waxman's 'sameness' requirement. As the FDA itself recognised, this requirement is important because "[c]onsistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart".(4) Eliminating the sameness requirement will cause confusion in the healthcare industry. Generic manufacturers will also be forced to engage in costly duplicative testing, thereby facing increased exposure to tort lawsuits.

The lawmakers' concerns were echoed by the pharmaceutical industry, as demonstrated in an 11-page white paper issued on January 29 2014. In the white paper, the Generic Pharmaceutical Association (GPhA) reproached the FDA for ignoring Hatch-Waxman's "delicate balance" between the brand name drug industry and the generic drug industry. It predicted that the increased cost burden will force some generic manufacturers out of the market.

The GPhA also accused the FDA of disregarding the possibility of generic drug shortages and higher costs. These costs would result from additional regulatory requirements and an exponential increase in litigation risk, which lends support to the conclusions reached in the Matrix study.

Comment

Generic drug manufacturers will feel an immediate impact if the FDA's proposed rule is adopted. However, the rule's effects on government programmes (eg, Medicare), private insurers, doctors, patients and the public will be much farther reaching, leaving no one untouched by increased costs. The GPhA's chief executive officer, Ralph Ness, said that the FDA should "work with all stakeholders and identify a course of action that does not put patient safety or patient savings at risk". As with any proposed rule, the FDA welcomes comments and has extended the comment period until March 13 2014. All affected parties are urged to submit comments at www.regulations.gov.(5)

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Endnotes

(1) 564 US, 131 S Ct 2567 (2011).

(2) *Id* at 2852.

(3) 555 US 555, 129 S Ct 1187 (2009), and *PLIVA, Inc v Mensing*.

(4) FDA Abbreviated New Drug Application Regulations – Final Rule, 57 Fed Reg 17950, 17961 (April 28 1992).

(5) Docket FDA-2013-N-0500.

Morrison & Foerster LLP associate Sara Bradley also contributed to this update.