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Dear Senators Wyden and Grassley,

Thank you for this opportunity to provide feedback regarding the report on "The Price of Sovaldi and its impact on the U.S. Health Care System" of December 1, 2015 (Senate Print 114-20), as referenced in your letter of January 21, 2016.

I have previously sent to members of your staff an email expressing my appreciation for their preparation of the Report on Sovaldi. The Report is a most valuable resource for researchers in the field of pharmaceutical regulation and it reflects a high level of objectivity and professionalism.

Your letter raises several specific questions regarding information that would be useful in further addressing policy issues raised by the Report. Like others with interests in this general subject matter area, I have written and published a number of books and papers regarding ways that mechanisms for promoting innovation in the pharmaceutical sector and making improved treatments available to the public at affordable prices might be improved. In this brief response, I confine myself to the attached paper (forthcoming article) that benefited particularly from the information and analysis assembled in the Report.

The attached paper, "Excessive Pharmaceutical Prices and Competition Law: doctrinal development to protect public health" (forthcoming UC Irvine Law Review, Volume 6, Issue 3, Spring 2017), recommends that US antitrust law, and in particular the Sherman Act, should be used to address excessive prices charged by pharmaceutical producers and suppliers. The article notes that US courts have been reluctant to address excessive pricing "as such". Federal courts have generally expressed the view that producers with lawfully secured monopolies should be allowed set prices however they wish as a reward for their skill, acumen or good fortune. The courts have been reluctant to evaluate whether prices are reasonable (or not) on grounds that judges are not specialized regulatory authorities. Federal courts and antitrust authorities consider that excessive prices may evidence underlying anticompetitive conduct that may be addressed by correcting underlying market defects or abuses. Excessive prices are not unlawful in themselves.

The attached article suggests that this judicial view is particularly problematic when addressing monopolists whose positions are effectively established by Congress by virtue of the Patent Act and its implementation. A patent (or regulatory market exclusivity) granted to a pharmaceutical company may confer a lawful monopoly. If the monopoly is lawfully obtained, there may not be a market defect for the courts to correct using existing antitrust doctrine. As a consequence, pharmaceutical companies may charge excessive prices without concern regarding whether their conduct violates antitrust law.

The attached article points out that the Sherman Act was adopted by Congress in 1890, and initially applied by the Supreme Court, to protect the public from abusive monopolists. The Supreme Court expressly affirmed protection of the public interest as the central motive of the antitrust laws. In its early days the Sherman Act was used to defend the public against high prices charged by railroad and oil barons. It was not adopted merely to address potential market defects.

Just so, the antitrust laws should be used today to protect the public from excessive prices charged by pharmaceutical companies under the guise of patents and regulatory market exclusivity. The attached article is not proposing some form of general price control, nor is it quarreling with prices that reasonably take into account risks associated with research and development necessary to develop and market new and improved treatments. The article is aimed at the type of pricing practices identified by the Report on Sovaldi -- prices set by investment bankers and financial engineers to press the absolute limits of public health system tolerance and to extract the maximum amount of financial gain possible without literally bankrupting the payors (including state public health authorities, federal government programs (like the Veterans Administration) and private health insurers.

Pharmaceutical originator companies shield their internal budget data, as Gilead has done with respect to development of Sovaldi. They argue that it is simply not possible to explain the cost of developing a new drug, and that it is sufficient for them simply to say that it costs “a lot”. Congress and the public are warned against seeking to look inside the “black box” of new drug development.

The refusal to provide information is in the interests of the companies. Pharmaceutical originator companies know their R&D costs, both in terms of successfully developed products and related products that do not succeed. Pharmaceutical companies have real budgets. Pharmaceutical executives do not write blank checks for their R&D departments.

The US government has a tremendous stake in understanding the costs of R&D on new drugs, and in understanding how pricing decisions are made. The Report on Sovaldi partially lifts the veil on one new drug that is priced excessively. Congress must do more to secure meaningful data on the costs of new drug development, and on how pricing decisions are made. A tremendous amount of US taxpayer money is spent on new drugs, and Congress should be trying to figure out where taxpayer money is going.

The attached article provides suggestions on methodology for determining how reasonable prices for new drugs may be determined, as a base for deciding whether the prices charged by producers may be excessive.

One reason for suggesting that the Sherman Act and excessive pricing doctrine should be applied in this area is that enforcement of the antitrust laws is not dependent on new legislation, and is not wholly dependent on enforcement actions brought by government authorities. Private litigants may bring

claims under the Sherman Act, and may recover triple damages. Successful private litigation, as well as exemplary cases by public authorities such as the Department of Justice and Federal Trade Commission, may be sufficient to bring some pricing responsibility and discipline to the pharmaceutical sector in the United States.

I once again express my appreciation to your staff for their work in preparing the Report on Sovaldi. The report is an important step in improving the public health system of the United States.

Sincerely,

Frederick M. Abbott

Appended article: Frederick M. Abbott, Excessive Pharmaceutical Prices and Competition Law: doctrinal development to protect public health, UC Irvine Law Review, Vol. 6, Issue 3, forthcoming Spring 2017