

BOOK REVIEWS, NOTES AND COMMENTS

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IL VALORE DEI FARMACI
Accesso alle terapie efficaci
e sostenibilità della spesa

Giuseppe Traversa
Roma: Il Pensiero Scientifico
Editore; 2024
242 p.
ISBN: 9788849007916
€ 25,00

*[The value of drugs.
Access to effective therapies
and sustainable spending]*

The book aims to tackle, in a comprehensive and multidimensional way, the complex process of evaluating the value of pharmaceuticals within the Italian regulatory framework – a topic of great importance for the sustainability of the National Health Service (SSN).

Giuseppe Traversa, with expertise and methodological accuracy, analyses the dynamics between innovation and sustainability, highlighting how these two concepts are often perceived as contradictory in the pharmaceutical sector. In fact, the financial balance of the NHS conflicts with the legitimate interests of pharmaceutical companies and the necessity to develop innovative drugs to meet the health needs of the population. While innovation should ideally yield benefits in terms of treatment efficacy and safety, it inevitably brings about an increase in costs.

The challenge, therefore, lies in being able to “pay” for a drug in proportion to the clinical benefit it offers, compared to the alternatives already available. This concept expressed through the definition of “place in therapy,” represents the core of the debate. The author emphasizes that, to assign an adequate value to a drug, it must be positioned along a continuum that stretches from therapeutic equivalence to true innovation – a task that he acknowledges is extremely complex.

A chapter examines the price negotiation process, shedding light on the interactions between the regulatory Agencies and pharmaceutical companies. In many instances, the regulatory evaluation does not meet the expectations of the companies, thereby lengthening decision-making times and further complicating the determination of a price based on the drug real therapeutic value. To fairly reward innovative drugs, there must be a shared definition of “innovativeness” and, consequently, a consensus on the principle that a drug offering no advantages over existing alternatives cannot be priced higher. Although this approach is theoretically sound, in practice it clashes with the difficulty of unambigu-

ously defining concepts such as “therapeutic overlap” and “marginal benefit.”

Another part of the book is dedicated to managed entry agreements (MEAs), instruments that have played a pioneering role in Italy in managing uncertainty. These agreements represent a pragmatic response to the problem of early access to drugs whose clinical efficacy is still being defined, allowing for risk mitigation for the payer through a shared acceptance of uncertainty. However, Traversa does not spare criticism of these instruments, highlighting their limitations and the decline in their use in recent years considering evidence that questions their actual capacity to ensure a proper evaluation of therapeutic value.

The analysis then extends to the discussion of real-world data (RWD) and real-world evidence (RWE). The author acknowledges the value of these data sources as a complement to randomized clinical trials, while reiterating that, whenever possible, the latter remain the gold standard for establishing the efficacy and safety of new treatments.

Throughout the book, the author follows a multidisciplinary approach, emphasizing that the process of evaluating and negotiating drug prices requires the synergistic contribution of medical, economic, statistical, legal, and pharmacological expertise and underlines that, in an era where an aging population and relentless technological progress further strain healthcare budgets, it is essential to integrate diverse perspectives to ensure equitable and sustainable access to care.

Emphasis is placed on the discussion of spending caps and the increasing demands for financial buffers by companies and Regions. Traversa analyses how, although spending caps serve as a safeguard for public finances, they also highlight a situation in which the expenditure for direct drug purchases consistently exceeds forecasts, thus underlining the urgency for structural interventions and systemic reforms to effectively govern pharmaceutical spending.

In conclusion, the book offers a comprehensive and critical overview of the challenges related to evaluating the value of drugs within a complex and ever-evolving regulatory environment. Its clear exposition and ability to integrate different perspectives make this work an important reference not only for industry professionals, but also, for prescribing physicians, and medical students. The reflections and proposals presented provide stimulating insights for a more balanced and transparent management of the relationship between innovation and sustainability, which is fundamental for ensuring access to quality care in a healthcare system under constant economic pressure.

Thus, Traversa contribution emerges as a valuable resource for both scientific and political debate, offering conceptual and operational tools to address one of the most pressing challenges of our time: reconciling therapeutic progress with the need to contain costs, while simultaneously maintaining a high standard of patient care.

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**NON È MAI MORTO
NESSUNO**
**Dagli impasti crudi
al microbiota, viaggio
nella microbiologia di tutti
i giorni**
Alessandro Mustazzolu
Milano: Gribaudo, IF,
Idee editoriali Feltrinelli srl;
2024
224 p.
ISBN 978-88-580-4898-6
€ 16,90

*[No one ever died from it:
from raw dough to microbiota,
a journey into everyday
microbiology]*

“Science isn’t finished until it’s communicated. The communication to wider audiences is part of the job of being a scientist, and so how you communicate is absolutely vital” [1]. So did Sir Mark Walport capture one of the core duties of scientists. This statement also reflects one of the primary missions of the European Union which, over the past 20 years, acknowledged that citizens are the ultimate beneficiaries of scientific initiatives, and accordingly implemented strategies to involve laypeople in the process of scientific discovery. Over the years, research programmes – from the original Framework Programmes to Horizon 2020 and later Horizon Europe – have progressively increased the dissemination requirements that researchers must meet to secure funding. While earlier initiatives were required to include some form of dissemination to the public, current ones are required to directly engage citizens at nearly every level of the activities, be it in the form of dissemination initiatives, involvement in guideline preparation, or active participation in data acquisition (i.e., citizen science). This effort has a dual aim: to encourage scientists to step out of their “ivory tower” and to raise public awareness of both the benefits of research and the rigorous methods researchers follow to achieve meaningful results. Complementarily, greater transparency will help taxpayers build trust in science and mitigate the scepticism that unclear communication may generate.

Ultimately, actively engaging the public in research efforts is expected to help mitigate the growing risks of fake news and conspiracy theories that exploit scientific jargon to mislead.

We believe that the book *Non è mai morto nessuno: dagli impasti crudi al microbiota, viaggio nella microbiologia di tutti i giorni* meets this aim. It exemplifies how scientists can foster meaningful dialogue with the general public to achieve the aforementioned goals. Alessandro Mustazzolu, microbiologist, is truly one of a kind – his strong research expertise (he is a Research Scientist of the Italian National Institute of Health) is matched by a dynamic and impactful presence on social media (over 68000 followers, and counting). He uses his network to educate the public as to the potential outcomes of a reckless consideration of the microbiological risks encountered during our daily lives (e.g., inaccurate handling of poultry, sanitization of surfaces, raw food and so on). Most importantly, Alessandro’s activity extends well beyond passive information to incorporate a constant (and to our view often thankless) interaction with his followers. In other words, he constantly answers followers’ questions with an unwavering commitment.

This book is a well-structured and highly entertaining reflection of his activities: Alessandro devoted each chapter of his book to answer everyday questions emerged in his interaction with social media followers. For example, Agnese is wondering how to deal with her mother allowing her grandchildren (Agnese’s children) to eat the raw shortcut pastry regardless of the potential dangers related to the ingestion of raw eggs. Using this and similar questions as a starting point, Alessandro guides the reader through the fascinating microbiological world that exists within our homes. Grounded in solid experimental evidence, he skillfully balances entertainment with education, raising awareness of the risks we encounter in daily life. And it’s not just about raw eggs – sausages and fish are also under scrutiny (sushi lovers may be disappointed, but it’s for their own good!). Besides providing “protocols-for-dummies” – like suggestions on how to manipulate and treat foods and beverages, Alessandro takes the opportunity to unfold some of the mysteries of microbiology and their impact on our health: listeria, salmonella, and botulinum will become familiar to the reader. As members of an institute that was originally established to fight malaria, we can do nothing but encourage everyone to read the chapter devoted to this disease. Therein, the reader will also access the fun fact of a Nobel prize that has not been awarded due to jealousy and bitterness.

Alessandro takes a tour of our entire homes, bedrooms included: and in this section, sex becomes the starting point to explain how some diseases may be sexually transmitted but also how our way to generate a progeny is linked to the microbial world. The reader will be surprised to know that our bodies host trillions of bacterial species. And the word microbiome, now pervasive even in TV commercials, will become intelligible.

While the topics covered in the book are numerous, they are all linked by an underlying theme: bias. This term is used to define a set of mental shortcuts that



we typically form (resting on scattered, limited, and inconclusive data) to inform our actions. The title of the book, which can be translated in “No one ever died from it”, encapsulates one of the most common biases: the survivorship bias. Since Agnese’s mother, and Agnese herself, did not experience any negative outcome following raw egg consumption, this habit has to be safe (we are biased to think that if something hasn’t harmed us before, it won’t harm us in the future). Alessandro is telling us that this is not the case and is encouraging us to handle our biases in a constructive way. And raw eggs are just one example.

This book has the potential to reach a large audience: not only the public which will learn how to minimise risks in their daily lives, but also scientists who will enjoy the rigour of the information presented in this book

(and the selected references too). Just don’t read it if your date is waiting for you at the sushi bar!

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